PROTOCOL

Evaluating the integration of the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) into primary care and its impact on patient treatment and care.

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LIST OF ABBREVIATIONS/GLOSSARY

Abbreviation	Explanation
ACP	Advance Care Planning
BMA	British Medical Association
BSA	British Social Attitudes Survey
CAG	Confidentiality Advisory Group
CCG	Clinical Commissioning Group
CI	Chief Investigator
CPR	CardioPulmonary Resuscitation
CQC	Care Quality Commission
CRN	Clinical Research Network
DMC	Data Monitoring Committee
DNACPR	Do Not Attempt CardioPulmonary Resuscitation
ECTP	Emergency Care Treatment Plans
ED	Emergency Department
GCP	Good Clinical Practice
GP	General Practitioner
GDPR	General Data Protection Regulation
HRA	Health Research Authority
ICF	Informed Consent Form
ICU	Intensive Care Unit
IRAS	Integrated Research Application System
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NPT	Normalisation Process Theory
PCN	Primary Care Network
PI	Principal Investigator
PPI	Patient & Public Involvement
POLST	Physicians Orders for Life Sustaining Treatment
RCGP	Royal College of General Practitioners
RCUK	Resuscitation Council UK
REC	Research Ethics Committee
ReSPECT	Recommended Summary Plan for Emergency Care and Treatment
R&D	Research and Development

SMG	Study Management Group
SOP	Standard Operating Procedure
SSC	Study Steering Committee
TEP	Treatment Escalation Plan
WCTU	Warwick Clinical Trials Unit
WMS	Warwick Medical School
WP	Work Package

1. BACKGROUND

When a person develops a life threatening condition or has a sudden deterioration in an existing illness rapid treatment decisions are needed. Often there is limited clinical information or information on what the individual's treatment preferences might be. Anticipatory treatment decisions and recommendations may improve this decision making process. Do Not Attempt CardioPulmonary Resuscitation (DNACPR) decisions are the commonest form of anticipatory treatment decisions but concerns exist about their use including:

- failure to consider CPR decisions before a patient deteriorates,
- lack of discussion with patients and/or their family,
- lack of transferability of forms between primary and secondary care and ambulance services(1,2).

A key concern is that a focus on CPR leads to lack of consideration of other treatments that may, or may not, be appropriate(3,4,5).

A more holistic approach to anticipatory decision-making for future treatments is captured in the concept of advance care planning. Advance care planning, defined as a process of formal decision making that aims to help people establish decisions about future care that take effect when they lose capacity(6), is recommended in NICE guidance(7) and in the UK national Gold Standards Framework for end of life care(8). While historically advance care planning has been seen as important for people approaching the end of their life, the Gold Standards Framework website notes that advance care planning can support people at any age or stage of health in understanding and sharing their personal values, life goals, and preferences regarding future medical care(8). While advance care plans include recommendations about specific treatments including CPR they have a broader scope. They can include preferences on place of death and other non-treatment aspects of care. Advance care plans are typically directed by the person although supported by, and often prompted by, health care professionals caring for them. Lund, in 2015, described two broad theoretical approaches to advance care planning,

1. a phenomenonological or psychosocial approach that sees advance care plans as patient driven, drafted in the patient's own environment and focuses on broad goals, and
2. a pragmatic or organisationally oriented approach that follows a trigger event, focusses on identifying specific treatment goals in the face of death and is documented and shared(9).

Emergency Care Treatment plans, sometimes called Treatment Escalation Plans, focus on treatment decisions in emergency or acute illness situations. Their aim is to make treatment recommendations that reflect the person's preferences and values, and are reached in discussion with the person or their family. However, the specific recommendations are made by the health care professional and are intended to guide future treating clinicians(10). Emergency care treatment plans would be conceptualised within the pragmatic approach described by Lund et al (9).

Another important distinction between advance care plans and emergency care treatment plans is that advance care plans ultimate focus is on end of life care preferences, an emergency care treatment plans focusses on steps to be taken in the event of an acute pathophysiological deterioration in which recovery is possible although may be unlikely(11). In the USA the Physician's Orders for Life Sustaining Treatment (POLST) has been adopted in 47 States(12). In the UK examples include a TEP used across

primary and secondary care in Devon(13), and an Emergency Health Care Plan as part of the Deciding Right initiative currently active in North East England(14).

In 2016, the Resuscitation Council UK (RCUK) led development of a new approach to support conversations about goals of care, and to provide guidance to clinicians about treatments, to be recommended in an urgent situation when the patient lacks capacity to decide for themselves (9). This initiative was in response to a growing concern regarding the use of DNACPR recommendations and informed by our evidence review(15).

Initially rolled out in Acute Trusts the Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) has now been adopted for use in primary care by several Clinical Commissioning Groups. Seventy percent of counties in England have now fully or partially adopted ReSPECT across primary and secondary care or are working towards adoption, and there is strong support for its uptake in primary care (personal communication). Initial adoption occurred in Acute NHS Trusts. We have just completed an evaluation of its use in acute NHS Trusts (16). However, there may be advantages to having these conversations in primary care. For example patients may have an established relationship with their GP, conversations can occur over an extended period, patients are less sick and more able to engage in discussion, and conversations can be placed in a wider context of advance care planning. A consultant participating in our current study commented to this effect:

"this is quite a serious and significant discussion … it should either happen when the person is comfortable in their own home or they have gone to see their GP" (17).

However, there are also potential difficulties in moving ReSPECT conversations to primary care; patients and families may be less ready to think about these things until a crisis emerges, GPs may be uncertain about hospital-based interventions, and both may have concerns about the effect of a conversation on the patient doctor relationship. The ReSPECT process aims to support patient involvement in decisions about their care but these conversations may also lead to distress or uncertainty for patients and their family(18). If forms are not completed and reviewed with diligence future treatment decisions may lead to less rather than more appropriate treatment.

The COVID-19 pandemic has precipitated an increased focus on the use of emergency care treatment plans in general and ReSPECT in particular. The high mortality in older frail people and in those with specific co-morbidities, few effective treatments, and restrictions on hospital visiting, focussed attention on the need for discussions about what treatments they would, or would not, want, or would be recommended should they develop COVID. GPs and hospital doctors admitting acutely ill patients were encouraged to have these conversations with patients early and to document the resulting treatment recommendations. This renewed emphasis on anticipatory decision-making was seen as supporting best practice in person centred care, and an opportunity to embed the principles and practice of advance care planning and emergency care treatment planning into clinical practice more generally (19,20). However, there were concerns that the method of implementation might lead to inappropriate use and resulting poor patient care. Doctors were expected to document conversations and treatment recommendations, including decisions about resuscitation and admission to hospital, when face to face contact between GPs and patients or their families was restricted. Examples of DNACPR and ReSPECT forms being completed without a conversation with the patient or their family were reported in the press leading to public concern (21) and statements from professional and regulatory organisations (22,23). The Care Quality Commission's interim report into its review of Do Not Attempt Cardiopulmonary Resuscitation decisions during the COVID-19 pandemic noted there was

confusion and miscommunication about the application of DNACPR decisions, with some evidence of unacceptable and inappropriate DNACPRs being made at the start of the pandemic. It also identified differing views on the extent to which people are now experiencing positive person-centred care and support in relation to this issue(24).The RCGP and BMA have recognised the challenges for GPs in having these conversations during a pandemic and have provided guidance to its members reiterating the requirement for individualised conversations about future treatment decisions (25,26). It is not clear what impact this experience, or the findings of the CQC's final report, will have on the use of advance care plans and emergency care treatment plans, including ReSPECT as the pandemic recedes.

GPs were being encouraged to use ReSPECT prior to COVID and this has accelerated during the pandemic. However, the rapid implementation under pressure of the pandemic risks inappropriate use which may have implications for future implementation. There is therefore a pressing need to explore how it currently does or does not work in primary care, the impact of the pandemic on its implementation, and implications for patients, their families and health care professionals.

1.1 Existing knowledge

In a scoping review to identify studies evaluating implementation of emergency care treatment plans including barriers to implementation, patient and provider experiences, and outcomes we identified four UK studies, three reporting on treatment escalation plans in single hospital sites (27,28,29). All reported that the treatment escalation plan increased appropriate decision-making around treatment escalation and resuscitation, although appropriate was not defined. TEPS were positively evaluated by staff. An evaluation of the first ReSPECT pilot in Scotland included 200 ReSPECT forms completed in a range of settings (hospital (83%), hospice and community), The study found that patients with a ReSPECT form were more likely to die in their preferred place of care and had a reduced chance of readmission within 3 months of hospital discharge. Patients and family (n=15) felt that discussions were open, honest and that they were involved. Staff (n=20, eight with experience of ReSPECT) were generally positive about the process (qualitative responses) (30). Challenges included time pressures, staff reluctance to initiate a conversation or lack of confidence to do so. A study currently being conducted by NIHR Applied Research Collaboration (ARC) West is evaluating use of ReSPECT in nursing homes(31). We are currently completing the first comprehensive evaluation of the ReSPECT process in secondary care(16). We have reported preliminary findings from interviews with secondary care consultants' in two acute NHS Trusts in England. We found that uncertainty about prognosis, constraints of time and external environment, and the need to minimise patient distress, influence prioritisation and content of conversations (17).

All but one of the other identified studies in our literature review related to the Physicians Orders for Life Sustaining Treatment (POLST) intervention or versions thereof and were conducted in North America. A 2015 systematic review of studies of the POLST programme (N=23) found that POLST was most commonly used in older white people who are near the end of life and that clinicians were generally positive about its use. However, they reported a wide range of challenges including lack of knowledge and training, discomfort with discussing issues raised, and problems using it to guide treatment (32). There was little evidence on whether POLST reflects patient or surrogate treatment preferences. The authors called for research to explore patients' and families' experiences of POLST and assess its effect on care outcomes. We identified 36 further studies published since this review. Two identified barriers to implementation of POLST at the systemic and individual level including

- lack of patient knowledge,
- reluctance to discuss end of life, uncertainty about prognosis,

- lack of time and concern about the physician patient/family relationship,
- lack of infrastructure and
- legislatory concerns (33,34).

Successful implementation was facilitated by standardised protocols or decision aids for conversations (35,36,37,38,39,40). Possession of a POLST form specifying limited or comfort level care was associated with reduced likelihood of admission to ICU or days spent in ICU although data were variable depending on reason for hospital admission and underlying medical condition(41,42,43). POLST was also associated with increased referrals to hospice and out of hospital death in people with cancer and Parkinsons Disease (44,45,46). Studies looking at POLST in nursing homes or elderly care facilities found a high level of consistency between POLST recommendations and subsequent treatment decisions(42,47,48,49).

As the literature on POLST is almost exclusively from North America and does not include primary care we considered wider literature on anticipatory decision making. Advance care planning has many synergies with ECTPs particularly in primary care and there is a large international literature on ACP, including some studies in primary care. We therefore reviewed this literature using as a starting point a 2018 overview of systematic reviews that included 80 reviews and over 1600 studies of ACP(52). We then searched PubMed for systematic reviews published since 2016 (cut-off date for the 2018 review) using the search terms advance care plan* AND implementation OR barrier* OR facilitator* OR outcome*. We identified a further 34 reviews. The 2018 review overview found some evidence of benefits including documenting of care preferences, dying in preferred place and health care savings, and that facilitators of effective ACP include provision of information by a knowledgeable person, transfer of ACPs across healthcare settings and moving ACP from a hospital to community setting(50).

Of the 39 reviews identified since 2016, 15 focussed on ACP in specific diseases including cancer, dementia, COPD and heart failure. Key messages from all reviews were similar to those found by Jiminez (50). A holistic, culturally sensitive and systems wide approach was seen as necessary for effective ACP (51,52,53,54) with education of both patients and health care professionals(55,56). Patients and families value honesty and openness in conversations (57,58,59) but there is a reluctance among health care professionals and patients to talk about end of life (60). ACP was felt to bring benefits including a greater sense of peace and less worry, but it could also be disruptive and distressing 18,58,61)). ACP was found to be associated with dying in their preferred place (59), reduction in hospitalisation rates and length of stay and invasive treatment and reduced health care costs (62,63,64). Three reviews looked specifically at culture and ethnicity in relation to ACP (65.66.67). Cultural factors reported as affecting ACP acceptability included religiosity, spirituality, trust in the health care system, social networks, and patient attitudes regarding decision-making. There was variable methodological quality of studies reported by most reviews. One review specifically looked at methodological quality of studies investigating concordance between ACP and end of life care. The proportion of patients who received concordant care varied from 14% to 98% but studies were methodologically poor (68).

We found two systematic reviews that focussed specifically on ACP and general practice (DeVlemenik 2013, (n=15)(69) Risk 2019 (n=54)(70). The 2019 review used an ecosociological framework to classify barriers and enablers to ACP's uptake at the individual, interpersonal, provider and system level. Key barriers identified reflected previous review findings and included lack of patient knowledge and trust, confusion over whose role it was to initiate the conversation, concern over impact in the patient doctor relationship, GP's lack of confidence and training, and lack of organisational support including

mechanisms for sharing ACPs across settings. The review also noted the paucity of research on ACP general practice and very few studies included the patient's voice. A 2016 scoping review of implementation studies of ACP in nursing homes (n=16) found variation in implementation strategies and outcomes with barriers to implementation including absence of physicians in the process, reluctance of staff, residents and families to initiate or participate in discussions and legal issues (71).

The literature on ACPs and POLST identified structured tools and protocols as a key enabler for implementation. The ReSPECT process and form, with the supporting educational materials provided on the ReSPECT website, could be characterised as such. However, a review that specifically looked at implementation studies of ACP using Normalisation Process Theory as an analytical framework concluded that structured tools were unlikely to be sufficient (10). The authors suggested that interventions most likely to be successful will need to make ACP workable within complex and time pressured clinical workflows. They developed four propositions about ACP normalisation which are relevant when considering normalisation of ReSPECT;

- Clinical and organizational pressures affect opportunities to initiate and operationalize ACPs.
- Prognostic uncertainty affects clinical decisions to initiate ACP conversations
- Responses of patients' and their families to initiation of conversations are unpredictable and emotionally complex
- Clinical and organisational factors intervene to confound elicited plans and preferences

Findings from our current evaluation of ReSPECT in secondary care support the first three propositions. Propositions two and three in this framework reflect the complexity, uncertainty and emotive nature of ReSPECT conversations. These kinds of conversations rely on a relationship of trust between the patient, their family and the health care professional. The literature on trust suggests that patient trust for their clinician has two elements, trust in their competence and trust that they have the patient's best interests at heart (72). Trust is necessary in situations of uncertainty, and anticipatory treatment decisions have a higher level of uncertainty than contemporaneous decisions as potential events and outcomes are in the future. In addition, at the time the recommendations take effect the patient will not be in a position to contribute to or modify decisions made. The limited empirical evidence on patient and family experiences of ACP suggest that they value honesty and transparency (57,58,659), seen as facilitators of trust, and studies focusing on culture and ethnicity in relation to ACP notes trust in the health care system as a factor in acceptance of ACP (65,66,67). There is mixed evidence on whether continuity of care facilitates development of trust in the patient doctor relationship. It will be important in the proposed study to explore how trust of patients' and their family in clinicians and in the health care system influences the ReSPECT process.

The policy aim for ReSPECT is that it should be normalised into everyday clinical practice. The proposed project will therefore evaluate the use of ReSPECT in primary care in relation to the Normalisation Process Theory framework. In doing so it will specifically consider the interactions between individual and system levels and include the patient voice, both identified as gaps in the systematic review of ACP in primary care (70).

1.2 Need for this research

From 2015 to 2035 there will be a >150% increase in number of older people with complex multi-morbidity (73). These people are particularly susceptible to sudden significant deterioration in their health resulting in emergency treatments and admission to hospital. Many will be unable to make a

decision regarding treatment at the time of the emergency. Half of the increase in emergency admissions between 2013/14 and 2016/17 came from people aged 65 and over, particularly those who are frail (74). The 2.8% of the older population who are care home residents account 7.9% of all emergency admissions for people aged 65 or older (75). In 2016 there were over 1.6 million emergency admissions in the UK for people in the last year of their life (an 8% rise since 2011) costing the NHS £2.5 billion and amounting to around 11 million days in hospital (76). While some emergency admissions in the last year of life are necessary most people prefer to die at home (77,78). Decisions around admission to intensive care are often made with no knowledge of the patient's values or wishes and may be influenced by a range of non-clinical factors leading to over or under treatment (79).

There is an ethical and professional obligation to balance benefits and burdens of treatment from the patient perspective(80). Anticipatory decision making using 'Emergency Care Treatment Plans' (ECTPs) can facilitate person-centred shared decision-making in the acute situation by enabling considered assessment of the benefits and burdens of a range of treatments taking into account what is important to the patient. If the ReSPECT initiative is effective it should improve patient care, fit with current policy on personalised care (81) and allow more effective use of NHS resources.

It could also improve the experience of people with Learning Disabilities and their families/carers. Health outcomes are often poor for people with LD because health professionals do not understand their needs (82-84). Obstacles include lack of education and training among health professionals, communication challenges, and/or a perception that individuals lack capacity because of their disability (85-86). Anticipatory care planning with people with LD is minimal due to a lack of confidence and awareness among medical staff (87-89). However, people with LD may particularly benefit from emergency care treatment planning as their needs and wishes are often not met in acute situations (83). There is a need to explore the views and experiences of people with LD with regard to anticipatory treatment planning and work with them to develop approaches that are relevant and accessible for them to engage with.

GPs who took part in focus groups for our evaluation of ReSPECT in Acute Trusts described a willingness to engage in the ReSPECT process, recognised that conversations should be embedded in clinical practice but suggested practical and cultural challenges to achieving this. They agreed evaluation of its use in primary care was needed. An early evaluation of its adoption across primary care, potential enablers and obstacles to implementation, and impact on patient care will provide evidence to inform successful and sustainable implementation, ensuring that potential benefits to patients and the health service are realised.

1.3 Ethical considerations

This study will be conducted in accordance with the NHS Research Governance Framework and the principles of Good Clinical Practice (GCP). As the study may involve some patients who by the nature of their underlying illness lack capacity, the requirements of the Mental Capacity Act (2005) will be observed. The study will comply with relevant Warwick Standard Operating Procedures (SOPs) and all data will be stored securely and held in accordance with Data Protection Act 2018.

This study raises a number of ethical issues given the sensitivity of the subject under investigation. The main ethical issues we have identified are as follows:

1.3.1 Recruitment and conduct of Interviews with patients and family members

ReSPECT discussions are inherently sensitive and emotive conversations. People who have a ReSPECT form completed may often be coming towards the end of their life and any ReSPECT conversation will be precipitated by an acknowledgement that an acute deterioration in health from which recovery may be unlikely is anticipated. Recruiting participants and conducting interviews will need to be approached with sensitivity. We have identified processes to avoid approaching a patient or member of their family who is in the last stages of life and to identify if a relative is bereaved prior to a follow up interview. The senior research fellow who will conduct the interviews will have either experience of or receive training in conducting sensitive interviews with patients and families and in assessing capacity to consent. Interviews can be stopped at any time should the participant wish to do so or becomes distressed. When a patient lacks capacity to consent to access to their ReSPECT form and medical records we will seek personal consultee agreement from their next of kin.

It is possible that a patient will be identified who had a ReSPECT form completed in hospital and may be unaware or have forgotten that this occurred. This could be distressing if they first become aware or re-aware of a ReSPECT form through a letter about a research study. We will where possible purposively select patients who have had a ReSPECT form completed in primary care to make this less likely. We will also develop a communication plan to ensure that any enquiries to the study team regarding an unknown ReSPECT form completion are responded to sensitively and the patient or their carer directed to the GP for further discussion.

1.3.2 Responding to distress of patients and family members during interviews

Interviews can be stopped at any time should the participant wish to do so or if they become distressed. Participants will be known to the health care professionals within the GP practice who can provide further support should the participant require it. We will also provide contact details for local support services identified through the practice. For bereaved participants we will offer contact details of local and national support services. If the researcher is concerned about a significant harm for an individual participant, for example if the participant discloses a suicidal intention, the researcher will discuss this immediately with either the WP lead or CI who will take action to ensure appropriate support is provided, probably through their GP. WMS has a standard operating procedure for responding to disclosures of this nature by research participants, which we will follow.

1.3.3 Concerns about unprofessional practice or safeguarding arising in the interview

If concern arises about unethical or unsafe clinical practice the researcher will consult the work package lead or CI who will decide if it is necessary to initiate action through normal professional channels, which is likely to be through the relevant GP practice. We think it is unlikely that serious unprofessional conduct will be observed or disclosed in this study. If any disclosures are made the participant (GP, care home staff, patient or family member) involved in the interview where this practice was revealed will be informed that this is happening. The need for a researcher to disclose any evidence of serious professional misconduct or safeguarding concern will be made clear in the relevant participant information sheets.

1.3.4 researcher safety during lone working

Some patient and family interviews may be conducted by the senior research fellow working alone visiting patient's homes. Our process for managing these events will comply with the University of

Warwick lone worker guidance and the University of Warwick SOP for risk assessment and monitoring in research studies which specifies conducting a risk assessment and the process for ensuring a 'buddy' system is in place for any lone worker activity. A named person will be the contact for the researcher when conducting research interviews as a lone worker, with agreed times for contact and steps to take if contact is not made.

1.3.5 verbal consent for informal conversations with practice staff (WP1)

When the researcher initiates or participates in informal conversations with practice staff members, the researcher will obtain and document verbal consent from the participating staff members to write up these conversations, or any part thereof (in quoted or paraphrased form), as field notes, to be used in data analysis. Obtaining verbal consent would allow us to maintain continuous transparency about the fieldwork process and ensure that practice staff members consent to each informal conversation, while minimising disruption to the informal conversation and their routine work. To ensure that participants can easily contact the researcher to withdraw their consent, the researcher will give their University of Warwick business card, which includes their email address and other contact information, to each clinical staff member who participates in an informal conversation.

1.3.6 Accessing medical records and ReSPECT forms (WP1 & 3)

We have received approval from the Confidentiality Advisory Group to use section 251 of the NHS Act 2006 to access medical records. Patients (and carers of patients who lack capacity) will be given the opportunity to opt out of this part of the study by the provision of an information leaflet explaining the study. We present the potential risks, mitigations and benefits of this approach below.

The main risk for copying and extracting data from medical records relates to a breach of trust / confidentiality through access to clinical records. We are mitigating the risk by (1) only reviewing sections of the record relevant to the research question (2) collecting the minimum amount of data to address this research question (3) anonymising copied/extracted data (4) making use of routine audit data where possible (5) ensuring staff collecting the data will have a duty of confidentiality through a contract with the hosting GP practice or care home. It is possible (although unlikely, given the existing duty of clinicians to consult patients), that an awareness of this research activity may prompt patients to raise questions about their overall treatment.

The direct benefits for individual research participants are limited to raising a general awareness about ReSPECT amongst clinical staff and patients. There will also be benefits for future patients through a better understanding of how ReSPECT is working in the NHS and social care.

Considering the risks, mitigations and benefits we assess the overall risks from this as low to negligible.

The research requires the research team to access the following information from the patients' clinical records

i) Information recorded on the ReSPECT form

ii) Clinical justification for a ReSPECT recommendation

iii) General information about the patient (full information is provided in section 5.3). The types of information required is e.g. demographic information, frailty index if recorded and

treatment/management decisions for an episode of significant illness within six months of the ReSPECT form completion.

Information will be copied or extracted from the ReSPECT form and GP medical records by NHS practice or research staff.

NHS staff or research nurse/researcher with a research passport/honorary contract with the practice will anonymise the data set before it is securely returned to the central research team at Warwick University for analysis.

A record of who the participant identification numbers have been allocated to will be kept at the research site in order to enable withdrawal of participants after the data has been collected prior to analysis. In the event a patient requests their data not to be included after it has been collected but before the data is analysed, we will treat this as if it were a withdrawal and their data will be removed from the data set.

Our approach seeks to balance respect for the patients right to information in their medical record being treated confidentially, a public interest in obtaining an unbiased sample to achieve a valid research outcome and consideration of practicable alternatives to obtaining consent. This part of the data collection is the subject of our application to the Confidential Advisory Group (CAG).

We consider the use of assumed consent model (sometimes called opt-out consent) as proportionate to (1) the level of risk involved (2)the likelihood of a biased sample with patients who are more likely to have a ReSPECT form completed and acted upon because of significant illness less likely to complete the consent process, (3) the burden to patients / relatives of going through a process of written informed consent.

Information leaflets about the study will be sent to patients / relatives with an accompanying letter from the GP practice. The leaflet will include information about the study, what information is being collected, that it will be anonymised before leaving the NHS site and securely transferred to the central research team for analysis. It will also include contact details for further information and how an individual can opt out of the study. The opt-out approach was developed with patient and public partners and implemented successfully in our previous study evaluating ReSPECT in acute NHS Trusts. previous studies (IRAS Project ID: 204688).

Practice level consent

Practice level approval for participation in the study (and sharing of documents relevant to the system approach to implementing respect) will be provided through site specific approval processes.

1.3.7 Involvement of people with learning disability in co-production workshops

The study includes a specific work package in which researchers will work with people with learning disability (LD) in a series of co-production workshops to develop resources and recommendations for the use of ReSPECT and ECTPS more generally. In recruiting and working with people with LD as part of the study we aim to balance being as inclusive as possible while ensuring that potential participants are making a free and informed choice to participate. For this work package we are working closely with CHANGE, a leading learning disability rights charity. CHANGE operates a co-working model, employing people with LD to co-run projects, co-deliver training and co-create accessible information.

They have extensive experience of recruiting people with LD to a range of projects and will be responsible for recruiting all participants for this work package. CHANGE will also work with the study team to produce Easy Read participant information leaflets and consent documentation to facilitate participation. A project manager from CHANGE will facilitate all meetings and workshops involving participants with LD and we will follow CHANGE's protocols for safeguarding and supporting people who may become distressed during the workshops.

1.4 Data Collection

Several modalities will be used for the collection of research data across the different work packages (Table 1). Full information is provided in the detailed description covering each work package.

Table 1 Summary of the main approaches by each work package

	Interviews	Case note review	Survey	Focus group	Audit data	Co-production workshops
WP 1	X				X	
WP 2	X		X	X		
WP 3		X				
WP4				X		X

Confidentiality: Any researcher(s) from the study research team needing access to patient records to support the data collection at sites will apply for a research passport/letter of access. When reporting the findings of the study, participants (GP practices, care homes, patients and relatives, practice staff, focus group/workshop participants) who consent or choose not to opt out of the medical case note review will be assigned a unique participant identification number. All results and findings reported will be anonymised, to ensure no individuals can be identified in the study.

Options for data collection depending on COVID-19 risks and regulations.

We plan to conduct all research activity remotely where possible and where we do not think it impacts on the quality of the research. We have identified two areas where face to face contact between the researcher and others conducting the research (practice and care home staff) or between the researcher and interview participants, may in some circumstances be desirable and where only virtual contact might significantly affect the research quality and opportunity for some people to participate. Therefore, we propose the following approach:

1. **Participant interviews**: Most interviews will be virtual. When government guidance permits meetings between people from different households, we will consider offering face to face interviews as an option to participants. For patients and families, participants will vary in terms of COVID risk status, problems with hearing, vision and dexterity, IT literacy, access to devices and for care home residents, current arrangements for visits. When arranging the interview,

we will negotiate with each participant the most appropriate way of conducting the interview. If a participant chooses face to face interview, and this would be compatible with government guidance at that time, we will offer this.

2. **Researcher presence in the practice to support notes extraction and informal conversations with staff**: When government guidance and local GP practice/care home protocols permit entrance of non-practice/non care home individuals to be present for non-essential activities unrelated to clinical/care, we will negotiate with the practice/care home about researcher presence on the site for limited research activity.

Where an activity is face-to-face current public health guidance at that time will be followed e.g. social distancing, hand sanitiser, face mask/visor, cleaning of surfaces and any recording equipment, researcher undertaking lateral flow tests twice weekly. Table 2 shows research activities which may be considered for a face to face approach (in red) and which will be conducted virtually throughout the study, depending on current government guidance at the time.

Table 2 Options for data collection depending on COVID-19 guidance

Research activity	Government guidance permits contact for non- essential activities	Government guidance restricts contact for non- essential activities
GP practice identification	Telephone/secure email	Telephone/secure email
Presentation to potential participant GP practices	Researcher joins a practice meeting via whatever channel currently in use by the practice (face-to-face/video-conference/teleconference)	Researcher joins practice meeting via video-conference or tele-conference
Identify care homes and practice protocols	Telephone/secure email	Telephone/secure email
PPI activity	Video-conference/email	Video-conference/email
GP patient register search	Practice staff using normal precautions for clinical practice Researcher in practice to support	Practice staff using normal precautions for clinical practice Researcher remote suppport
Interviews with patient/carers living at home	Face to face inside or in secluded private garden OR Video-conference/telephone	Video-conference/telephone
Interviews with patients/carers living in nursing and care home	Face to face in line with care home protocols OR Video-conference/telephone	Video-conference/telephone
Interviews with GPs, nursing and care home manager, faith leaders	Face to face OR Video-conference/telephone	Video-conference/telephone
Conversations with practice staff	Face to face	Telephone
Focus groups	All participants join via video-conferencing OR face to face in line with venue protocols	All participants join via video-conferencing
Co-production workshops and reference group meetings for WP4	All participants join via video-conferencing OR face to face in line with venue protocols	All participants join via video-conferencing
Copying and deidentifying patient records and sending securely to study team	Practice staff using normal precautions for clinical practice OR researcher following practice protocols	Practice staff using normal precautions for clinical practice
Collecting ReSPECT form copies from care and nursing homes	Research team requests a member of staff of care/nursing home copy respect forms and send to practice	Research team requests a member of staff of care/nursing home copy respect forms and send to practice
Stakeholder conference	Presentations including touch point film/audio recording will be available to participants to view prior to the meeting.	

	Feedback from small groups to all participants will be via written summaries agreed by small groups and posted for all participants to view and post comments.	
	All participants join via video-conferencing OR face to face in line with venue protocols	All participants join via video-conferencing

1.5 Data Management

Data collected during the study will be handled and stored in accordance with the 2018 Data Protection Act and Warwick Clinical Trial Unit Standard Operating Procedures.

No personal identifiable data will be transferred between GP sites and the University of Warwick, between CHANGE and the University of Warwick. The detailed data management processes are in the descriptions of each work package that follows.

Disclosure of confidential information

If during data collection a participant raises any issue which may jeopardise the safety of the participant, the researcher will follow local local safeguarding processes, usually reporting the issue to the GP lead at the practice (WP1) or discussing with the project lead in CHANGE (WP4).Participant information sheets will include information about the disclosure of such information. If the researcher identifies an issue which raises concerns regarding professional misconduct that could result in a significant risk of harm to patients generally the researcher will discuss this with the work package lead. If the work package lead agrees that there is a cause for concern they will inform the GP practice, care home as appropriate in accordance with local policy on raising concerns.

1.5.1 Data storage

All essential documentation and study records will be stored by WMS in conformance with the applicable regulatory requirements and access to stored information will be restricted to authorised personnel. Any paper data forms, field notes, meeting notes, or other documents will be stored in a lockable filing cabinet in a secure room, to which access is restricted to authorised personnel. Electronic data will be stored in a secure area of the computer with access restricted to staff working on the study.

1.5.2 Data access and quality assurance

Study participants will be assigned a unique study identifier. Each site will maintain a confidential and secure list of patient identifiable information (name, date of birth, identification number) for the purposes of audit / quality assurance.

Once the study has been completed the records will be destroyed according to University of Warwick and or local site SOPs. The CI and the study manager (or staff they delegate this role to) will have access to the final study data set from all five work packages. Access requests from both co-investigators and external parties will be considered by the CI. A formal process will be developed by the study team to facilitate such requests and decisions. Any data shared will be anonymised and transferred as per University of Warwick SOPs with data sharing agreements in place.

1.5.3 Archiving

Study documentation and data will be archived for at least ten years after completion of the study. Research sites will archive documentation following their local policies.

1.6 End of the Evaluation Study

The study will officially end on the last day of funding, although dissemination of results will continue beyond that date.

Since this study is not implementing any intervention, it is unlikely to be stopped prematurely, unless funding is ended early. If several or all of the research sites in WP1 and 3 withdraw the ReSPECT process during data collection this could result in these aspects of the study ending prematurely or partially completed, unless replacement sites can be found within the time constraints of the project. The Research Ethics Committee will be notified in writing if the study has been concluded or terminated early.

2. STUDY SUMMARY

2.1 Aims and objectives

This study is a mixed-methods evaluation of the ReSPECT process for adults in primary care to determine how, when, and why it is used, and what effect it has on patient treatment and care.

Objectives

1. To understand how ReSPECT is currently used in primary care from the perspective of patients, their families, clinicians, and care providers
2. To describe the views of patients, the public, primary and community health care professionals, and home care workers on emergency care treatment plans in general and ReSPECT in particular
3. To identify enablers and obstacles to embedding ReSPECT in primary care practice
4. To explore the impact of ReSPECT on patient treatment decisions
5. To understand how health and social care professionals can optimally engage people with LD in the ReSPECT process and coproduce relevant support materials.
6. To develop a consensus on how ReSPECT should be used in primary care

The study consists of five work packages corresponding to our objectives:

WP1: A qualitative study using interviews with GPs, patients and their families/carers, and managers of care homes to explore how and why ReSPECT conversations occur and recommendations are made, their ethical basis and the experience of patients and their families of the decision-making process.

WP2: Focus groups with health care professionals, home care workers and members of patient and community groups to explore their views on the principles and practice of ReSPECT and other forms of anticipatory decision-making.. Interviews with faith leaders to explore the extent that the values

underpinning the ReSPECT process reflect or are dissonant with specific faith traditions. A national survey of public attitudes to ECTPs and ACP, and a national survey of GPs to explore their experience and views of anticipatory decision-making.

WP3: A quality assessment of ReSPECT forms and qualitative analysis of perception of congruence of ReSPECT recommendations and treatment and care decisions using data from interviews with GPs, patients and care home staff.

WP4: A series of co-production workshops with adults with learning disability to explore their understanding of and views on emergency care treatment planning and to co-create resources to support engagement of people with LD with ReSPECT and emergency care treatment planning more generally. Focus groups with carers/relatives of people with a learning disability to capture their views and experiences of emergency care treatment planning.

WP5: A synthesis of key findings from the study and a stakeholder meeting drawing on experience based co-design to identify strategies to support integration of the ReSPECT process to primary care practice.

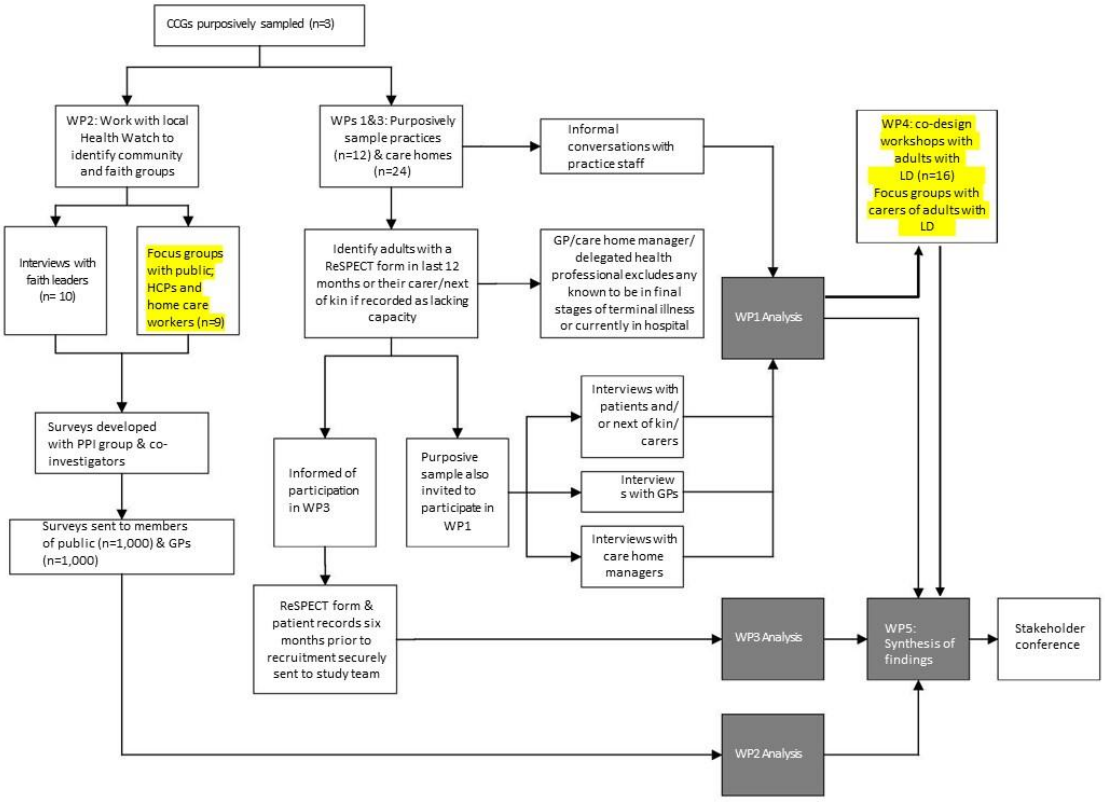


Figure 1 Study Flow Diagram

2.2 Design and theoretical/conceptual framework

Our overarching theoretical framework is Normalisation Process Theory (NPT). We wish to investigate to what extent ReSPECT is embedded in routine primary care practice and how it is perceived and enacted by health professionals and patients. NPT characterises a set of mechanisms (coherence,

cognitive participation, collective action and reflexive monitoring) that influence the embedding of new interventions or processes into clinical practice (90,91).

We will ask how do clinicians, patients and their families:

1. conceptualise ReSPECT (coherence)
2. initiate or engage with the process (cognitive participation)
3. use the process and the documentation (collective action)
4. evaluate the impact of ReSPECT and how it changes behaviour (reflexive monitoring)

NPT has successfully been used in a review of the implementation of ACPs to understand how they are implemented and embedded – normalised – into clinical practice (9). This review developed the following propositions about ACP normalisation:

1. Operational contexts are under pressure. Clinical and organizational pressures and the availability and preparation of staff affect opportunities to initiate and operationalize complex interventions like ACPs.
2. Patient trajectories are uncertain. Prognostic uncertainty is an important factor that affects the clinical decision to initiate discussion of ACPs with patients and their significant others.
3. Negotiations have unpredictable outcomes. Responses of patients and their significant others to the initiation of ACPs are unpredictable and emotionally complex.
4. Advance Care Plans may not be actioned. The operational outcome of ACPs are unpredictable because clinical and organizational factors that intervene to confound elicited plans and preferences.

We will test these propositions during our interviews and focus group work.

3. WORK PACKAGE 1: EXPLORING THE EXPERIENCES OF PATIENTS, CARERS AND CLINICIANS

3.1 Research questions

This interview study will seek to answer the following questions:

1. What patient characteristics are associated with completion of a ReSPECT form in primary care?
2. What are the experiences of patients, their families/carers, GPs and care home managers of being involved in the ReSPECT process?
3. What are the enablers of and obstacles to implementing the ReSPECT process in primary care?

3.2 Setting

Twelve GP practices from across three Clinical Commissioning Group (CCG) areas, or organisational equivalent at the time, in England that have adopted ReSPECT at least 12 months previously. CCGs will be purposively sampled to aim for diversity of geographical location sociodemographic profile, and time since implementation of ReSPECT.

3.3 Recruitment of GP practices and care homes

Within each CCG or the equivalent current organisation, we will work with the local primary care clinical research networks (CRNs) and primary care networks (PCNs) to seek expressions of interest

from GP practices. We will purposively sample a minimum of 12 practices from those who express an interest in participation, based on size, geography (rural/urban) ethnic diversity, and socioeconomic status. We will increase our sample beyond 12 if we do not identify sufficient patients with a ReSPECT form to meet our sample size for WP3. We will use practice postcodes to select purposively for socioeconomic and ethnicity profile using data from Office for National Statistics. For selected practices, we will present the study to practice staff supported by written information and seek consent from a designated PI for practice participation.

For each of the recruited GP practices, we will seek to identify two care homes where the practice is the primary practice for the home. Care homes will be purposively sampled to include both residential and nursing care homes. We will contact the care homes through the practice and present the study to the care home staff supported by written information and seek consent from the home manager for participation in the study.

To place our qualitative work in context, in each practice we will identify any practice protocols for initiating/reviewing ReSPECT or other ECTP/advance care planning documents.

3.4 Recruitment and consent: individual interviews

3.4.1 Patient and family/carer interviews

We will aim to recruit up to 48 patient/carers across all sites with representation from three groups, which are people:

1. living in a care home
2. living at home, identified as nearing the end of their life (but not in the final stages of a terminal illness)
3. living at home, not identified as nearing the end of life.

All patient or carer facing documentation will be developed in collaboration with our PPI advisory group.

Recruitment through GP practices: A member of practice staff will search the patient register to identify all adults in the practice known to have a ReSPECT form completed in the previous twelve months. We will work with the practice to identify the most appropriate search method. As an additional process we will ask care homes who have agreed to participate in the study to identify residents who are registered with the relevant practice and who have had a ReSPECT form completed in the last 12 months and cross check with the practice that none of these people have been missed in the original practice search. The lead GP for ReSPECT/ACP or delegated health professional for the project in the practice will check the list of patients to exclude those who are known to be in the final stages of a terminal illness (expected to die within the next six weeks) or currently in hospital. They will also check for each eligible person whether they are recorded as lacking capacity and if so whether there is a specified carer or next of kin associated with ReSPECT form completion. If a patient record is flagged as the patient having opted out of their data being used for purposes other than direct clinical care the patient will be excluded. People living in participating care homes will be approached through the practice or the care home.

Following screening by the GP, eligible patients with a ReSPECT form completed in the last six months will be purposively sampled for WP1 based on age, sex, ethnicity, efrailty score and whether they are

resident in a care home. A pseudonymised spreadsheet containing these variables (no personal identifiers) for potential participants will be generated by practice staff and transferred securely to the study team. The study team will identify participants to be invited for interview (WP1) in addition to being informed about the notes review study (WP3) with an opportunity to opt out. If response rate to invitation to interview is low in our initial practices we will amend our approach in further practices recruited so that patients invited for interview (WP1) will not be included in WP3 (notes review) under section 251 of the NHS Act access to medical records. Therefore they will receive a simplified invitation letter referring only to the interview study and the option of consenting to a researcher accessing their ReSPECT form. The remaining patients in the eligible sample will be sent information about the notes review study (WP3). The relevant information packs (invitation letter and brief information leaflet) will be provided to the practice who will then post these to sampled patients to inform them about the study inviting them to contact the research team if they are interested in taking part. For people whose first language is not English we will offer the opportunity of an interpreter to facilitate the interview. If the person is known to lack capacity in relation to ReSPECT or other health care decisions the person named in relation to the ReSPECT form or the next of kin/carer recorded in practice records will be sent the information leaflet and letter of invitation. If the practice does not have a postal address for the named carer/next of kin for a patient who lacks capacity the practice will send the study information by email (if email address available) or if the contact details are telephone only, a member of practice staff will telephone the carer/next of kin and ask if they would be prepared to receive information about the study and provide their postal or email address for this purpose. Potential participants will be asked to contact the study team to express interest (post, free phone (text or audio), email) including their contact details and preferred channel of communication with the research team (phone/text/email).

Participant selection and consent: Depending on the number of expressions of interest we will purposively sample across practices aiming for diversity of age, gender, ethnicity, usual living arrangements (home/care home with, or without, nursing), We estimate that to gain sufficient information power (92) from second interviews we need to recruit a total of 48 patient/family/carers. This allows for 50% attrition between first and second interviews leaving 8 per Group at second interview.

The researcher will contact those who have expressed an interest in participating to discuss the study and arrange an interview. This will be via their preferred channel of communication or for care homes by phone (with our without care staff support as needed). Prior to the interview, a full information sheet will be sent to the participant. For participants with capacity we will ask them if we can also interview any family member who was involved in the ReSPECT discussion. If they agree, we will provide a separate information sheet and consent form for the family member. If the person is known to lack capacity related to the ReSPECT conversation, the person who took part in the ReSPECT conversation or their next of kin will have been invited. If it becomes clear in the initial discussion with the researcher that the patient lacks capacity to consent to the research the researcher will ascertain if the carer was involved in the ReSPECT form completion and if so seek consent for an interview with the carer. We will, in line with the Mental Capacity Act 2005 section 32, seek personal consultee agreement from the carer/next of kin of any patient who lacks capacity that the person would not object to the carer being interviewed in relation to their ReSPECT form completion.

We will offer patient participants the opportunity to have a family member present for support during the interview. We aim to make this offer to the patient when arranging the interview, so they are able

to make their decision independent of their family. We will ask the patient/carer or relevant care home manager to locate, where possible, the ReSPECT form to prompt the patient/carer memory of the ReSPECT process. Consent will be obtained prior to the start of each interview. At the first interview, we will seek permission from the participant to contact them and/or their main carer/next of kin if relevant in six months-time to arrange a second interview.

We will interview each participating patient/carer initially and after 6-9 months. During the second interview we will explore whether their ReSPECT form has been changed in the intervening period, whether they have had any significant illness episodes and if so whether the ReSPECT recommendations were helpful in guiding decisions about their treatment. As many participants may be in the last year of their life some participants may have lost capacity, be in the final stages of their life, or follow-up interviews may be conducted with recently bereaved carers. We will check with the GP before making contact for a second interview and approach this with utmost sensitivity. If a participant has lost capacity we will, in consultation with the GP, consider approaching the carer to see if they would agree to be interviewed. Participants will be reminded of the study and sent a follow up interview information sheet. If they agree to take part in a second interview the researcher will arrange this at a convenient time and location for the participant. Consent will be taken prior to the interview as for the initial interview. We have experience of interviewing bereaved relatives in this process can also be cathartic for the bereaved (93). Participants will receive a shopping voucher (Love2shop voucher) for £20 in payment for their time.

We will give participants the option of spreading the interview over more than one session. This may be a session with several short breaks or, it may be several short sessions held over several days. We want to offer this option as interviews can be tiring for the participant particularly when conducted via telephone or videoconference.

3.4.2 GPs interviews and fieldwork conversations with practice staff

In each practice, we will interview up to three GPs in the practice who are involved in leading ReSPECT conversations. In some practices a senior nurse may be responsible for leading ReSPECT conversations and completing forms. In these practices we will seek to interview any senior nurse who has this role. An information sheet will be provided and, if the person agrees, a time will be arranged for the interview and consent obtained prior to interview. We will ask them to review up to three ReSPECT forms that they have recently been involved in completing and any relevant clinical notes, in advance of the interviews to prompt their memory of the ReSPECT process they carried out.

We will carry out brief conversations (5-10 minutes, not recorded) with other members of the practice team, for example practice nurses, practice manager, receptionist, asking them about their awareness/use of ReSPECT, and how the process runs in the practice. If COVID regulations allow, a researcher will spend one or two days in the practice taking opportunities to speak to practice staff at a time convenient to them. Practice staff will be provided with information leaflets about the study in advance. The researcher will obtain verbal consent and record this in the field notes. Staff will be given the researcher's contact number so they can contact the researcher if they wish to withdraw from the study after the conversation has taken place.

3.4.3 Nursing and care home manager interviews

We will invite the managers (or senior members of staff) of care homes linked to participating practices to take part in an interview about their general experience of ReSPECT and of how clinical decisions are made for residents with a ReSPECT form. Managers will be informed about the study by the relevant GP practice and if they express an interest in participating will then be contacted directly by the research team who will provide a more detailed information sheet. Managers may pass this information to senior members of staff who may be seen as a more appropriate person to provide the relevant perspective during an interview. Those who express an interest will be contacted by the researcher to discuss the study and arrange an interview. Remote consent (for video or telephone interviews) or written consent (if it is possible to conduct face to face interviews) will be obtained before the interview.

3.4.4 Expanded recruitment for patient and care home staff interviews

If response to invitation to interview is low for patient/relatives or care home staff using the recruitment methods described above we will expand our approach to advertise the study more widely through care home networks to seek expressions of interest from care home staff, care home residents who have a ReSPECT form, and relatives of care home residents who have been involved in a ReSPECT conversation involving their relative. We will work with care home networks and care home organisations to seek their support to publicise the study to care homes within their networks/organisations. Care homes expressing an interest in the study will be contacted by a study researcher to discuss how the care home can advertise the study to staff, residents and relatives. The researcher will provide written information about the study and a poster that can be displayed in the home. The researcher will also offer to visit the home to speak to staff and where possible residents and relatives to tell them about the study. If a resident, relative or member of staff is interested in learning more about the study they will be able to contact the research team directly.

The researcher will contact those who have expressed an interest in participating to discuss the study and arrange an interview. This will be through their preferred channel of communication (telephone, video call or in person). We will offer resident participants the opportunity to have a family member present for support during the interview. Prior to the interview, a full information sheet (plus Easy read version for resident participants) will be sent/given to the participant. Consent will be obtained prior to the start of each interview as outlined in section 3.5.

Participants will receive a shopping voucher (Love2shop voucher) for £20 in payment for their time.

3.5 Consent process

If an interpreter is required for patient or family interviews, we will arrange this through the practice using the NHS contracted interpreter service used for clinical consultations. Written consent will be obtained immediately prior to all face-to-face interviews. For interviews occurring via video or audio call remote verbal consent will be obtained. When the interview time and date is confirmed a consent form will be sent to the participant prior to the interview together with a full information sheet. Before starting the interview, the researcher will answer any questions the participant has, then go through the consent form with the participant. Remote verbal consent will be formally documented by the researcher, including consent to record the interview. The potential participant will be asked to verbally consent to each line on the informed consent form during the video/audio discussion. The researcher will initial and date each line of the consent form and then they will sign and date the

completed consent form. The participant will receive a copy of the informed consent form by post or email following the interview.

For conversations with practice staff, the researcher will obtain verbal consent from the participating staff members to write up these conversations, or any part thereof (in quoted or paraphrased form), as field notes, to be used in data analysis. All field notes will anonymise participants and exclude or alter identifying information; pseudonyms will be used throughout, and the staff members' names will not be recorded.

3.6 Withdrawals

Participants can withdraw from the interview study up to three weeks following the interview without prejudice. Beyond three weeks the data will have been transcribed and entered into the analysis process so it will not be possible to extract it from the analysis.

Participants will be given the contact details for the research team who they may contact at any time during this period to inform the team they wish to withdraw consent. Their wishes will be recorded in the Study Master File using their study ID and their data removed from the study.

3.7 Data collection

3.7.1 Describing patient characteristics

We will work with the practice staff to collect pooled anonymous data on;

- practice population demographics
- number of ReSPECT forms recorded
- for people with ReSPECT form: age; gender; ethnicity; eFrailty index (generated from routine practice data); type of residence (care/nursing home or own home/family home) and where ReSPECT form completed (if recorded)

This element of data collection is part of our application to CAG to permit a study researcher to support practice staff.

We will work with individual practices to develop the best identification processes using practice electronic records and other practice systems. A data collection spreadsheet will be completed for all patients with a ReSPECT form completed in the previous 12 months to include age, gender, ethnicity, efrailty index, and whether resident in a care home. This will be held in the practice. The data spreadsheet will be anonymised with personal and study identifiers removed and transferred securely to the study team at WMS. We will present descriptive statistics on these data.

Interview process

Interview topic guides have been developed with input from our clinical co-investigators and our patient and public advisory group. As we collect data we will review and revise topic guides to ensure we are obtaining the richest possible data whilst remaining sensitive to participants. We will keep the interview open for participants to talk about ReSPECT and advance care planning in whatever order they wish and enable them to talk about issues not covered by our topic guides, whilst aiming to cover all our planned topics. We will audio or video record all interviews with participant consent. Where consent to recording is not given, we will take field notes and expand the field notes directly after the interview. We would like to use brief clips from interview recordings as part of our experience led co-

design work at our stakeholder conference. We will seek consent to use clips of interview recordings from participants prior to any interviews. We will check with participants, or next of kin if appropriate, whose recording we wish to use that they are happy with the recording clip prior to using it for the meeting.

3.7.2 Patient and family/carer interviews

First interview: At the start of the interview we will ask if the patient/carer has located the ReSPECT form and if they have, suggest they look at it to remind them of the ReSPECT process. Using the NPT framework to guide our data collection, we will frame our questions to reflect NPT elements. We will ask them:

- What they understand about the ReSPECT process and form *(coherence)*
- Their views on the ReSPECT process, when they consider their ReSPECT form should be reviewed and who should initiate this review, when and how it should be acted on(*cognitive participation)*
- To describe the ReSPECT process from when it was first considered or mentioned through to completion of the form and any updating of the form *(collective action)*
- Thoughts and feelings the process engendered; whether the process changed how they viewed themselves, their health/illness, and the prospect of their death; whether they think it resulted in a change to the care, and treatments they received and how they viewed these; their sense of trust in their clinicians and in the health service more generally including whether they trust that the ReSPECT form will receive attention once completed; how the ReSPECT process could be improved. We will ask whether they have been involved in any other advance care planning discussions and whether COVID-19 has had any impact on their thinking about ReSPECT or advance care planning in general *(Reflexive monitoring)*.

Second interview: The researcher conducting the interview will re-read the first interview transcript and make notes to inform their prompts during the second interview. Where a first interview participant has died we will acknowledge this at the start of the interview with their carer. We will ask participants about major changes to the patient's life context and health/illness including any illness/treatment events since the first interview, including further experience of the ReSPECT process/review. If they have further experience with ReSPECT we will explore this in a similar way to the first interview and prompt for any differences compared to the first interview. Where participants have experienced illness/treatment events we will explore their perception of any influence during this event, of their completed ReSPECT form. With all participants we will explore whether and how their reflections on the ReSPECT process and its impact have changed and what influenced these changes.

3.7.3 Interviews with GPs and conversations with practice staff

GP Interviews will be conducted as described for patients and family/carer interviews.

We will design our GP interviews to deepen our understanding of how GPs operationalise the ReSPECT process within their complex and time pressured clinical workflows using the framework of NPT (10,80). We will ask the GPs to familiarise themselves with the ReSPECT forms of any patient-participants, or other ReSPECT forms they have completed to use as an aide memoire in the interview. In the first part of the interview we will:

- Explore their understanding of the ReSPECT process and form *(coherence)*

- Ask them to give an account of up to 3 ReSPECT processes they were involved in including the ReSPECT process for a patient participant if they were involved in completing the relevant form. We will inform them of this request before the interview so that they can refresh their memory of the case. We will prompt for why they decided to start each process, how they set up the process, their experience of any conversation with patient and family, their experience of form completion, storage and accessibility for future reference, consideration of reviewing the completed ReSPECT form and how the ReSPECT form influences the care they provide for the patient *(cognitive participation).* We will ask the GP not to disclose any personal identifiable information relating to patients during the interview.

- Ask them to describe how the practice organises the ReSPECT process *(collective action).*

- Explore thoughts and feelings the process engendered; whether the process changed how they viewed their patients and themselves; whether they think it resulted in a change to the care and clinical interventions they provide and how they viewed these; any impact on the trust between patients and themselves or the health service more generally including whether they trust that the ReSPECT form will receive attention within general practice and other parts of the health service once completed; how the ReSPECT process could be improved. We will ask whether they have been involved in any other advance care planning discussions and whether COVID-19 has had any impact on their thinking about ReSPECT or advance care planning in general *(reflexive monitoring)*.

In the second part of the interview we will ask the GPs to reflect on their experience with ReSPECT using the four propositions developed by May et al (11). We will ask the clinician to what extent it reflects their current experience and what is missing.

During fieldwork, in conversation with practice staff we will explore their understanding of the ReSPECT process and form, their role (if any) in the ReSPECT process, how the practices organises and documents the ReSPECT process, and whether they perceive any impacts on patients or staff.

3.7.4 Nursing and care home managers

Interviews will be conducted as described for GPs, patients and family/carer interviews. The questions will map to the NPT framework and aim to understand their perceptions and experience of the linked general practice's ReSPECT process. We will explore:

- Their understanding of the ReSPECT process and form *(coherence).*
- Their role in the ReSPECT process including whether they initiate the process by suggesting it to a resident/family member or GP, *(cognitive participation)*
- Collective action: how the practices organises the ReSPECT process in relation to their nursing/care home and how the home stores the forms and uses them when the resident is ill *(collective action).*
- Whether their involvement with ReSPECT has changed their thoughts or behaviours and whether they perceive any impacts on their residents or staff of the ReSPECT process. We will ask whether they have been involved in any other advance care planning discussions and whether COVID-19 has had any impact on their thinking about ReSPECT or advance care planning in general *(reflexive monitoring).*

We will draw on existing evidence related to ACP in care homes to further guide out interview questions and prompts (94, 95, 96).

3.8 Data Management

Data collected during the study will be handled and stored in accordance with GDPR, the 2018 Data Protection Act and WMS Standard Operating Procedures. Prior to participant consent to participation all personal data will be held by the relevant GP practice or care home. The practice will complete a data collection spreadsheet in which each patient identified with a ReSPECT form completed in the previous 12 months will be entered and given a unique identifier code. This database will be used to send invitation letters to patients and their family, and to provide aggregate anonymous data to the Warwick co-ordinating research team. Participants who contact the research team and agree to take part in the study will, with their agreement, have their name and contact details stored securely on the University server for the purposes of contacting them again to arrange an interview.

Consent for interview will be taken and interview data will be collected by researchers from the co-ordinating study team. Consent forms will be stored at Warwick University in the Division of Health Sciences in a locked filing cabinet in a locked room with access limited to the core study team.

Interviews will be recorded, transcribed verbatim and anonymised with each participant being assigned a unique interview ID. Transcripts will be stored in a separate electronic folder to the database of names and contact details of participants. Recordings of interviews will be collected on encrypted devices then securely transferred on the same day to the secure university server. After transfer the recording will be deleted from the recording device. Transfer to any transcription services will be done via a secure system and according to Warwick data transfer SOPs and a data sharing agreement. Any handwritten field notes will be kept in a locked filing cabinet in a locked room in the University. If on site field work is permitted, field notes recorded electronically will be on an encrypted, password protected laptop while the researcher is at the site and then uploaded to secure university servers the same day**.**

Transcripts will be uploaded to NVivo software for data management together with any field notes. All transcripts and notes of conversations will be coded; 30% independently by a second researcher. Data analysis will be concurrent with data collection and initial analysis will inform subsequent data collection.

3.9 Analysis

Data analysis will be carried out by the study research fellows. Analysis codes and emerging themes will be discussed at regular analysis meetings with the core research team (FG, AS, CH, RS). Following data collection at the first four practices we will hold a data analysis meeting with members of our lay advisory group and our PPI co-investigator. Their input into the analysis will contribute to refining the interview guides for subsequent interviews and ensure that the patient perspective is not lost in our interpretation. Data from interviews sourced through wider care home networks will be flagged during analysis and reporting to check for any differences with the interviews sourced through GP practices.

Using framework analysis (97) we will seek to understand how and why the implementation of ReSPECT varies, including identifying dissonance between accounts of different actors: patient, family/carer, GP, nursing/care home manager. We will test and extend exiting theory and evidence on the enablers of, and obstacles to, implementing advance care planning in primary care and understand how it applies to the ReSPECT process (69). We will tease out implications for trust between patients

and their healthcare providers and within wider society, refining or adding to existing theory (71). We will explore the data for explicit and implicit ethical concerns, using the approach of grounded moral analysis to explicate the ethical dimensions of the ReSPECT process (98). We will identify dilemmas faced within the ReSPECT process and analyse their ethical dimensions. We will describe how participants negotiate the complex issues related to the ReSPECT process in the time-limited context of primary care (9). In particular, to inform future educational materials, we will bring to light how participants seek to simplify aspects of the ReSPECT process through the use of heuristics or simple tools/rules and critically evaluate them.

4. WP TWO: UNDERSTANDING THE WIDER CONTEXT OF RESPECT IMPLEMENTATION (OBJECTIVE 2)

In this work package we will engage the public and health professionals in reflection and debate about the concept and use of Emergency Care Treatment Plans in general and ReSPECT in particular. As the use of ECTPs relates to ethical issues and death, we will engage with representatives of all relevant faith communities. Based on findings and those of WP1, we will develop two questionnaire surveys. One for the public, and one for primary and community health care professionals.

There are two research strands in this WP:

- Focus groups/interviews
- Surveys.

4.1 Research question

What does the wider public and primary and community health and social care professionals think about the concept and use of emergency care treatment plans?

4.2 Focus groups and Interviews

4.2.1 Methods

We will run focus groups in each of the three primary care areas, with members of the public with an interest in healthcare (30 participants across all groups) and with non-GP health and social care professionals working in the community or in hospital emergency departments (30 participants across all groups). We will also run up to three focus groups (one in each of our areas) for home care workers advertising through local home care providers in each of our three areas to recruit 6/7 care coordinators and/or home care workers per area (total approx. 20 participants).

We will also interview local faith leaders in these areas.

4.2.2 Recruitment

By contacting community groups with an interest in health. we aim to recruit people who are keen to engage in discussion about the ReSPECT process including its complexity, sensitivity, and ethical considerations, and willing to challenge the current approaches where necessary and suggest change. For the focus groups we will speak to each participant in advance of the focus group and send text message or email reminders to reduce no-shows.

Members of the public with an interest in health care:

We will work with the regional Health Watch for the relevant CCG area to identify community groups, including local faith groups, and patient support organisations with which to advertise the study. We will provide a poster about the study, an invitation email and brief information leaflet describing the study for circulation through these groups. We will ask those interested in participating in a focus group or learning more about the study to contact the research team. We will also advertise through GP practice patient groups and other GP venues such as local GP run vaccination centres. From those expressing an interest we will purposively sample to reflect the sociodemographic and ethnic profile of the community covered by the CCG until we have at least 10 people willing to participate.

Health and social care professionals:
We will advertise the study to health and social care professionals working in the community or in emergency departments through a variety of means, including advertising through local branches of professional organisations relevant to primary and community health and social care in each CCG area, including organisations for nurses working in the community, paramedics, care workers/managers, community physio- and occupational therapists, and community palliative care professionals. We will also advertise to ED clinical staff through local hospital ED departments and emergency care networks. We will ask any health and social care professional from the relevant groups who is interested in participating to contact the research team. From those expressing an interest we will select to ensure diversity of professional background, until we have at least 16 professionals willing and able to attend in each CCG area.

If we are unable to recruit sufficient numbers of participants for focus groups we will also offer an invitation to individual interviews to the same sample populations.

Faith leaders:
We will interview up to ten faith leaders across the three areas. We will work with the relevant Health Watch in each area to identify the prevailing faith groups. The study will be advertised to Faith Leaders through a variety of means, including via community groups and through University and hospital-based chaplaincy services. We will invite a range of faith leaders in the community to participate in an interview. We will provide an information leaflet and invitation letter/email text for this purpose. For those people who contact the research team to express interest the researcher will discuss the study, answer questions and if the person agrees to participate will arrange a time for the interview.

Faith leaders and participants in focus groups/individual interviews will receive a shopping voucher (Love2shop) in payment for their time at INVOLVE rates; currently £22 per hour. Participants will also have travel expenses reimbursed.

4.2.3 Consent

The researcher will contact potential participants, answer any questions about the study and check that they are able to attend the focus group. We will send each participant a more detailed information sheet with a contact telephone number to use if they have any further questions. Two weeks prior to the focus group we will send participants a briefing pack about the ReSPECT programme and a summary of findings from initial analysis of WP1 data. Consent will be obtained by the researcher prior to the focus group, either in person or remote verbal consent obtained if the focus group is to be held online. Once consent has been documented the researcher will talk through a brief demographic questionnaire with the participant. This will record data on age, gender, sexuality, disability, and ethnicity. It will be made clear to the participant that they do not have to answer any of these questions if they prefer not to.

4.2.4 Withdrawals

Focus group participants will be able to withdraw their data from the study up to three weeks following data collection (that is prior to analysis), by contacting the study team.

4.2.5 Data collection

Focus groups: An experienced facilitator will conduct each focus group, with a researcher present to take notes. Prior to starting discussion, the facilitator will briefly present what was in the briefing pack as a reminder and to frame the discussion. Focus group members will be prompted to discuss the following questions:

- What are the benefits for patients, carers, the health service, and wider society of the implementation of ReSPECT?
- What are the dis-benefits of ReSPECT?
- What gets in the way of implementing ReSPECT in a way that optimises its use and value, including access to forms and transfer between health and social care organisations?
- How can the dis-benefits of ReSPECT, and challenges to its use be mitigated?

Interviews with faith leaders: These will follow a similar format to the focus groups. We will ask them to consider the discussion topics used for the focus groups. In addition we will:

- Explore how the values embedded in ReSPECT sit with key values of their faith e.g. treating people with dignity, respecting their autonomy, appropriate use of modern medical technologies and prevention of unnecessary harm and suffering.

- Explore areas where the faith's teaching supports the premise of ReSPECT or could cause challenges for people following that faith and any thoughts on how to mitigate these challenges for both patients and clinicians.

4.2.6 Data Management

Focus group and interview data will be managed in the same manner as described for interview data in WP1.

4.2.7 Analysis

We will use Framework analysis (89) to develop themes where there is consistency of opinion in relation to the use of ReSPECT and importantly, themes about which there is some tension or diversity of opinion. This tension or diversity may be within a focus group discussion, within what individuals talk about in relation to their family/community/faith group, or identified through comparing data from different focus groups/interviews. From this we will identify the key issues of consistency and importantly for the survey, issues where there is of tension/diversity. It is these latter issues that will form the focus of the surveys.

4.3 National surveys of public and GPs

4.3.1 Method

Informed by our early qualitative work we will work with our PPI advisory group to identify key questions to measure public awareness and acceptability of ECTPs. Questions are likely to cover use of Emergency Care Treatment Plans or ReSPECT, views on advance decision making (timing, relevant medical conditions, content of decisions/recommendations), and how likely participants are to complete an Emergency Care Treatment Plan.

Again, informed by our qualitative work we will work with our GP co-investigators and PPI advisory group to develop a questionnaire survey to measure the views of GPs nationally regarding the use of Emergency Care Treatment Plans including ReSPECT, in primary care. We will measure their knowledge of Emergency Care Treatment Plans and ReSPECT, views on their use in primary care, and how likely they are to complete an Emergency Care Treatment Plan for their patients.

4.3.2 Sample and data collection

We will outsource the surveys to specific purpose designed survey providers as a cost and time efficient approach to obtain representative data.

Public survey: We will commission the National Centre for Social Research to include our questions in the annual British Social Attitudes Survey (BSA). The BSA is the UK's longest-running survey of public opinion. It is viewed as the authoritative barometer of public attitudes by Government, academia and the media. It provides a high quality nationally representative attitudinal survey with a stratified sample based on postcode and including face-to-face data collection using computer assisted personal interviewing and pen and paper self-completion. New questions are tested in two pilots before use in the survey. We will commission our questionnaire items to be presented to 1000 participants.

GP survey: We will distribute the survey through a specific GP survey platform, medeConnect GP Omnibus, a monthly online survey of UK GPs. We will refine our questions using think aloud interviews with a small number of GPs and pilot the finalised questions with a sample of GPs prior to distribution. The survey provides data on commissioned questions presented to a regionally representative sample of 1000 GPs including partners, salaried non-principals and locums.

4.3.3 Data Management

Anonymised clean data sets from both surveys will be transferred securely from the survey company to Warwick University where they will be stored as password protected files on the university server accessible only to the core study team. A data sharing agreement will be in place between the survey organisation and the University. No personal data will be transferred. Any concerns participants had about their anonymised information being included in the survey will have been addressed by the organisation collecting the data at the time. Withdrawal will not be possible as only anonymised survey data will be provided to the study team. The data will be analysed by the study team statistician.

4.3.4 Sample size and analysis

We will analyse associations between the survey outcomes using regression models fitted to our outcomes of interest with covariates such as: age, gender, presence/type of chronic disease, functional status (patients), time in practice and practice size (GPs). The most important outcome is the binary outcome 'whether they would complete an emergency care treatment plan' (for themselves if public survey and for their patients if GP survey) for which we will fit a logistic regression model.

For our primary analysis we will dichotomise responses to our 11 point numerical rating score. Scores of <5 we consider as being 'unwilling' and i score is ≥5, as being 'willing'. The minimum sample size available for either survey is 1,000 responses. There is little additional benefit from a greater precision for a larger survey. For each of the surveys, in case of the binary outcome, if 50% (or 60%, 70%, 80% and 90%) of participants consider completing the form, this would ensure 6.2% (or 6.1%, 5.7%, 5% and 3.7% respectively) precision. This is a very good precision for such a study.

In a secondary analysis we will investigate 'how willing patients are to complete an emergency care plan on a scale of 0 till 10'. We consider this outcome to be continuous and fit a regression model to investigate associations between the covariates of interests and this outcome. Similar linear models will be fitted to other secondary outcomes. A sample size of 1,000 will give us ample statistical accuracy for these analyses.

5. WP THREE. INVESTIGATING CONGRUENCE BETWEEN RESPECT RECOMMENDATIONS AND TREATMENT DECISIONS: AN ANALYSIS OF PATIENT RECORDS (OBJECTIVE 4)

5.1 Research question

Our research questions for this WP are:

- What is the quality of completion of ReSPECT forms in primary care?
- To what extent do treatment decisions in an acute or emergency situation reflect the recommendations on a person's ReSPECT form?

5.2 Method

Retrospective analysis of patient records and ReSPECT forms; qualitative analysis of interview data from GP patient and care home staff interviews.

5.3 Recruitment

In each of our 12 participating practices we will use the list obtained in WP1 of people with a ReSPECT form recorded. A member of practice staff will identify all adults (18 and over) in the practice with a ReSPECT form completed in the previous twelve months and use the same checking processes as in WP1 prior to mailing invitation letters to all identified patients, or if the patient lacks capacity, the person whose contact details are on the completed ReSPECT form. As an additional process we will ask care homes who have agreed to participate in the study to identify residents who are registered with the relevant practice and who have had a ReSPECT form completed in the last 12 months and cross check with the practice that none of these people have been missed in the original practice search. A purposive sample of patients with a ReSPECT form completed in the last 6 months will also be invited to take part in the interview study (WP1). Participants recruited to the interview study can choose to opt out of the notes evaluation.

The practice will send a letter to the patient, or for patients who lack capacity the family member recorded as their carer in relation to the ReSPECT form or their designated next of kin/carer in the practice record, informing them about the study. Information will include, the purpose of the study, the information that will be collected, and how it will be anonymised before secure transfer to the

study team. The letter will include details of the ways in which the person can let the study team know that they do not want their medical records to be used in the study. Each information sheet and response form will have a unique study identification code which will be used by the study team to inform the practice if a person informs them that they do not wish to be included in the medical record review. No personal identifiable information will be transmitted to the central study team.

5.4 Withdrawals

A record of who the participant identification numbers have been allocated to will be kept at the research site in order to enable withdrawal of participants who opt out. No data will be collected from medical records for four weeks after the information letters have been posted to enable time for patients to opt out. In the event a patient requests their data not to be included after it has been collected but before the data is analysed, we will treat this as if it were a withdrawal and their data will be removed from the data set.

5.5 Data collection

A copy of the ReSPECT form and print outs of the patient record since ReSPECT form completion including hospital discharge letters and ED correspondence up to six months post ReSPECT completion will be generated by a member of practice staff or study researcher with a research passport. Each record copy will have personal identifiers removed and be given the participant's unique identifier code. The copy record will be matched with the patient's ReSPECT form (similarly de identified and coded) and then transferred securely to the study team. This element of data collection is subject to our application to the Confidentiality Advisory Group.

We will ask the care home to make a copy of the form, remove all personal identifiers, and transfer this electronically through a secure system to the study team. The participant unique ID code (allocated when the participant was added to the practice held database of patients with ReSPECT forms) will be added to the ReSPECT form so that it can be linked with the patient record.

5.6 Data Management

Relevant sections of patient records will be printed by a member of practice staff or study researcher with a research passport and all personal identifiers removed and a study code assigned. Record print outs will be linked to the relevant ReSPECT form. Each anonymised record will then be transferred securely to the University and stored either in a locked filing cabinet in a locked office (hard copies) or on a password protected secure database on the University server (scanned electronic copies).

5.7 Amendment to protocol following data collection at five sites.

Our original sample size calculation for the analysis of congruence between ReSPECT recommendations and subsequent clinical decisions assumed that 70% or patient records with a completed ReSPECT form in the previous twelve months would have an acute event within six months of form completion, and that congruency between recommendations and decisions would be 75% (Hickman in a study in nursing facilities in the USA found a congruency of 74% between POLST forms and later treatment decisions about choices about comfort care (47). Based on these assumptions we required 289 sets of records with a completed ReSPECT form and an acute event within six months of form completion (413 participants recruited across 12 practices). However, data collection in our first

six practice sites identified a substantially lower than expected number of completed ReSPECT forms, and an acute event rate within 6 months of ReSPECT form completion of 24% (expected 75%). Following discussion with the Independent Study Steering Committee and the funder it was agreed that the original sample size could not be achieved within the original research design. This the congruence analysis has been removed from the protocol and further collection of clinical records suspended. Collection of RESPECT forms for analysis will continue and a qualitative analysis of perception of congruence will be data from GP, patient and care home staff interviews (WP1). It is anticipated that approximately 100 completed ReSPECT forms will be collected for analysis across all practice sites. All included ReSPECT forms will be reviewed using the evaluation tool that we have developed in our recently completed study of ReSPECT in secondary care to assess quality of completion of each section of the form.

5.8 Assessing feasibility of congruence analysis using care home records

At the request of the funder alternative approaches to obtaining sufficient data for a congruence analysis were considered by the project management team. They concluded that the most likely feasible approach would be to conduct a prospective study based in care homes of the congruence of care and treatment decision making with ReSPECT recommendations using care home records. This approach would require a different study design with primary recruitment of care homes. Before embarking on a large scale study recruiting care homes a feasibility study will be conducted within the current project. The feasibility study will be conducted within the overall time line and budget of the current project and has been approved on these terms by the funder.

5.8.1 Objectives of feasibility study

Aim

To assess the feasibility of conducting a national study of care home records to analyse congruence of ReSPECT recommendations and subsequent treatment and care decisions for residents.

Objectives

- To estimate the percentage of care home residents with a completed ReSPECT form.
- To identify the frequency of acute medical events or clinical deterioration recorded within six months of a ReSPECT form completion.
- To assess the quality of care-home records description of treatment and care decisions made for acute medical events or deterioration.
- To identify the process of retaining and accessing records of residents who have died for retrospective review of treatment decisions.

5.8.2 Methods of feasibility study

Recruitment

We will work with the ENRICH team in West Midlands to recruit three care homes to the study. These care homes will not be linked to the GP practices in the current study. An initial approach from ENRICH via email or telephone call to research active care homes in their network will provide brief information about the study and its context within the wider project. Care homes can express an interest through ENRICH or by directly contacting the study team. For those care homes expressing an interest we will

provide a detailed information sheet and arrange a meeting with a senior member of the study team. We will seek to recruit care homes to reflect diversity of size and geographical location.

We will seek approval from the Confidentiality Advisory Group for an amendment to our existing approval to access patient records without explicit consent. The care home staff will check their record of residents who have opted out of their data being used for research using the national data opt out to ensure only those residents who have not opted out are approached. The study team will provide participating care homes with information letters about the study for all residents, and for the designated next of kin of those residents who the care home manager assesses as lacking capacity to understand the nature of the study and make a decision about participation. The care home staff will deliver the information letter either in person to residents or by post or electronically to their designated next of kin. Information will include, the purpose of the study, the information that the researcher will have access to, and that no personal or specific information will be copied or transferred from the record The letter will include details of the ways in which the person can let the study team know that they do not want their care home records to be used in the study. Each information sheet and response form will have a unique study identification code which will be used to record opt outs. No personal identifiable information will be transmitted to the central study team.

A record of who the participant identification numbers have been allocated to will be kept at the care home to enable withdrawal of participants who opt out. No data will be collected from care home records for four weeks after the information letters have been delivered to enable time for residents or their next of kin to opt out.

Data collection

Four weeks after delivery of the information letters a study researcher will visit the care home and identify the records of all residents who have not opted out of the study. For each resident the researcher will check the care home record and not in a field spreadsheet the following:

- Presence of a completed ReSPECT form
- Any record of acute medical event or significant deterioration in clinical condition within six months of ReSPECT form completion and number of events if greater than one)
- Is the record of decisions made related to this event sufficiently detailed to enable an analysis of congruence with a ReSPECT recommendation (eg does the decision specify any treatment given or reasons for decision not to escalate treatment)

No personal identifying information or specific information about treatment decisions will be recorded. Study specific identifiers will be removed from the spreadsheet before saving the field spreadsheet on the University server.

The researcher will also identify with the care home manager the process for archiving and retrieval of care home records of deceased residents.

Analysis

From the information collected we will be able to assess feasibility of conducting a large-scale national study of care home data to analyse the congruence of decision regarding emergency treatment and care with ReSPECT recommendations for residents in care homes., including an estimate of the care home recruitment target; willingness of care homes to participate, and research staff time and resources required.

6. WP4 CO-DESIGN OF RESOURCES TO SUPPORT ENGAGEMENT FOR PEOPLE WITH LEARNING DISABILITY

6.1 Research questions

Our research questions for this work package are:

1. What are the views of people with learning disabilities about emergency care treatment plans in general and the ReSPECT process in particular?
2. What are the views of carers of people with learning disabilities about emergency care treatment plans in general and the ReSPECT process in particular? What might be the challenges for people with learning disabilities and those working with them to access and engage with emergency care treatment planning?
3. What kind of information, processes and support around emergency care treatment planning and ReSPECT would be useful for people with learning disabilities and those caring for or supporting them?

6.2 Coproduction process

6.2.1 Methods

We will use coproduction methods that foreground the lived experiences and voices of people with learning disabilities to co-create resources to support engagement with ReSPECT and Advance Care Planning (ACP). We will work with CHANGE, a leading learning disability rights charity. CHANGE operates a co-working model, employing people with learning disabilities to co-run projects, co-deliver training and co-create accessible information.

6.2.2 Recruitment

Reference group

A core group of five individuals with a learning disability will work with CHANGE and the wider study team to design the coproduction workshops. They will review/advise on findings from each workshop, integration of findings into overall study, and final outputs of the work package. They will meet eight times during the project face to face in Leeds at CHANGE premises (if government Covid guidelines allow this to be done safely), and, if they wish, attend the stakeholder conference to present outputs. We will advertise through CHANGE's networks for adults (aged 18 or over) with a learning disability. We will provide introductory text about the study to seek expressions of interest and ask anyone interested in learning more to contact CHANGE. The CHANGE project lead will contact anyone expressing an interest to explain more about the study and their potential involvement. If the individual is still interested further written information comprising a participant information sheet with attached consent form will be provided via email or in the post and a second contact will be arranged (either by telephone, face to face or virtual platform, at the individual's expressed preference) to confirm if the person is willing to participate as a reference group member, and to seek consent. If requested, individuals will be able to visit CHANGE premises before consenting.

Inclusion criteria

Aged 18 years or over
Has capacity to consent to take part in the reference group
Ability to meet face to face in Leeds, (with support from CHANGE in arranging travel if required)

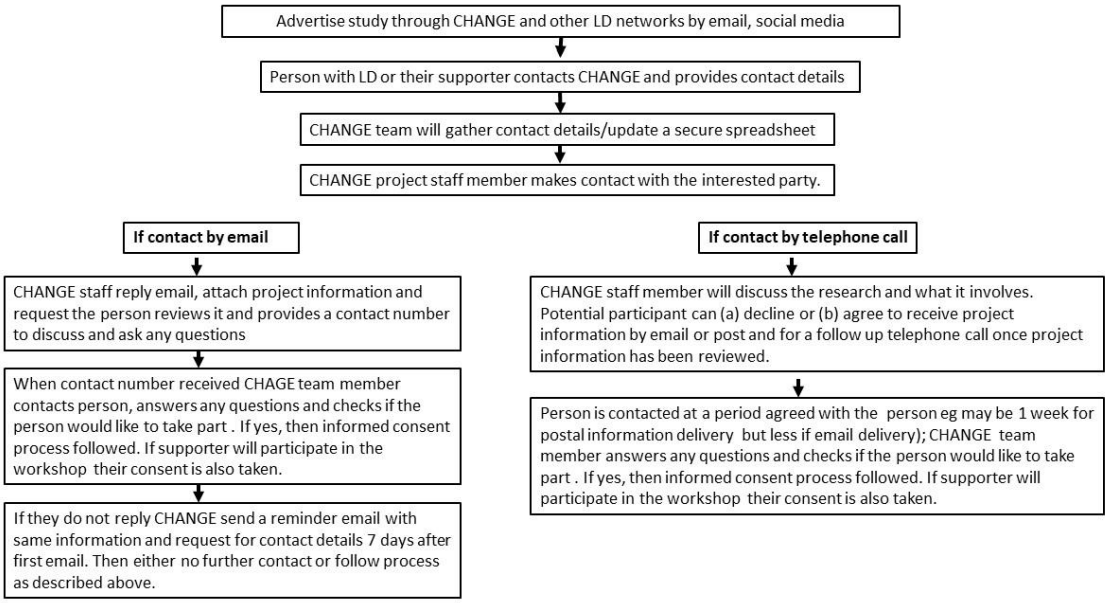
Co-production workshops

We will work with CHANGE and other learning disability organisations or networks nationally to advertise the project to people with a learning disability. We will an invitation email about the project for circulation through these groups and their social media. We will ask those interested in participating in the workshop series or learning more about the study to contact the project lead at CHANGE by telephone or email. The CHANGE project lead will respond to anyone expressing an interest to explain more about the project and answer any questions. Further written information will be provided and a second contact will be arranged to seek consent to participate in the co-production workshop series. Prior to obtaining consent the project lead will check that the person has read the information sheet, that any questions have been answered, and the person understands what is involved in workshop participation. Verbal consent will then be obtained and documented. The project lead will have experience of taking informed consent and assessing capacity to participate in research. We will recruit up to sixteen participants with a learning disability with the aim of having up to eight participants in each workshop series (two series of five workshops running in parallel). If participants require supporters present to be able to participate we will also take consent from the supporters as they may affect or contribute to the workshops. CHANGE will enable loan tablets to them for the duration of the 5 workshops.

Inclusion criteria

Aged 18 years or over
Has capacity to consent to participate in co-production workshops
Resident in England
Has internet access and is able to use online platforms either themselves or with a supporter.

Flow chart outlining approach to recruitment



6.2.3 Informed Consent

Reference group and co-production workshops, participants and supporters

Consent will be obtained prior to commencement of workshops or reference group meetings. A full information sheet and consent form will be provided to participants before the consent conversation occurs. Remote verbal consent for workshops will be obtained as these will occur online and participants will be recruited nationally. Consent for participation in the reference group may be in person or remote depending on preference. The CHANGE project facilitator will answer any questions the participant has, then go through the consent form with the participant and (if necessary) their supporter. For remote consent the potential participant will be asked to verbally consent to each line on the informed consent form during the video/audio discussion. The person taking consent (CHANGE project facilitator) will initial and date each line of the consent form and then they will sign and date the completed consent form. The participant will receive a copy of the informed consent form by post or email following the consent process. Once consent has been documented the CHANGE project facilitator will talk through a brief demographic questionnaire with the participant. This will record data on age, gender, sexuality, and ethnicity. It will be made clear to the participant that they do not have to answer any of these questions if they prefer not to.

At the beginning of each meeting/workshop the project lead/facilitator will check that all participants confirm their consent to participate and for the meeting to be recorded. Some participants may wish to have someone to support them with participation in the workshops, for example support with use of video technology or support with communication about meeting logistics. The research team will facilitate this and seek consent from any supporter who will be present at the workshops or reference group.

6.2.4 Reference group meetings

The reference group will consist of five individuals with learning disabilities who will work with CHANGE and the wider study team to design the coproduction workshops. They will meet eight times during the project and, if they wish, attend the stakeholder conference to present outputs.

Meeting one: This will involve informing members about research and the type of research we are doing; ReSPECT and emergency care treatment planning in general; the current project evaluating ReSPECT in primary care, and the specific goals of the co-production work package that they will be advising on. The aim will be to provide members with an understanding of the aims, context and content of the co-production process for this project.

Meeting two: The group will advise on the organisation and content of the series of workshops with a focus on the initial co-production workshop, reviewing and commenting on material and proposed activities for the workshop.

Meetings 3-7: The group will review a summary of the outcomes of the relevant workshop, comment on process and outcomes, and advise on process and content of the next workshop.

Meeting 8: The group will review a summary of the co-production process and outcomes and advise on how this should be integrated into the overall study findings for the stakeholder conference.

We will seek consent from members of the reference group to record the reference group meetings. Recordings will not be transcribed but will be used to supplement field notes during the analysis. The data from these meetings will contribute both to the overall findings of the ReSPECT evaluation and to our evaluation of the process of the co-production.

6.2.5 Co-production workshops

Five coproduction workshops will be held with two groups of adults with a learning disability (total 10 workshops). They will be iterative, and each workshop will include time/space to collate emerging reflections, recommendations and suggestions regarding ReSPECT. Workshops will cover:

Workshop 1. Introducing the workshop format, communication and confidentiality. Introducing research and the kind of research we are doing. Introducing ReSPECT and emergency care treatment planning; what is the aim of ReSPECT; who might it be for; when are ReSPECT plans currently used; information from previous research on emergency care treatment planning; information about the wider ReSPECT project.

Workshop 2. Understanding the ReSPECT process; what is the ReSPECT process; who can initiate a conversation; when is it usually done, what effect does it have on treatment and care; how is it reviewed; what are the potential benefits for people having a ReSPECT form; what are the concerns about this process. We will use data from our current interview study with GPs, patients with a ReSPECT form and their families as a resource for this workshop.

Workshop 3. Revisiting the ReSPECT process and exploring views about ReSPECT and ACP; what do the group think about ReSPECT, its aims, how it might be used and when; what are the benefits or challenges of this process for people with learning disability; what might be useful to support people with learning disability accessing or engaging with the ReSPECT process.

Workshop 4. Developing recommendations and resources to support use of ReSPECT with people with learning disability; what do health and social care professionals need to know or do to support people with learning disabilities in relation to emergency care treatment planning and ReSPECT? What information would be useful for people with learning disabilities; what form should information take? What is needed to support ReSPECT conversations; what safeguards should be in place to prevent misuse.

Workshop 5. Finalising recommendations and resources. The groups will review the recommendations and resources developed following the previous workshop and comment/suggest changes.

Workshops will occur online and will be facilitated by CHANGE. Workshops will be convened at intervals appropriate to avoid recall problems, and to allow time for analysis of key findings and their review by the reference group in between each workshop.

6.2.6 Responding to participant distress or safeguarding concerns

Discussing decisions about future illness and potential decisions about life sustaining treatment may be distressing for participants. The facilitator will be alert to any signs of distress during the reference group meetings and workshops, looking out for signs of distress, including, distressed speech, body language or somebody leaving an in-person meeting, or someone leaving an online platform. The facilitator will manage the conversations to mitigate distress, acknowledging the

difficulties, moving the conversation on as appropriate. Prior to the meeting the facilitator will remind participants that these discussions may make them feel uncomfortable but that it is a safe place, people will respect one another, safeguarding protocols are in place and people are free to leave at any time. Within a session, participants will receive a debrief at the end of each session, to check in with how people are feeling, if they have any other thoughts and signposting will be suggested as necessary. Workshops also end with a light-hearted activity or mindfulness/self-care sessions, which helps people leave on a positive note and increase the likelihood of negating the rumination of negative thoughts.

If a participant signs off or leaves the room, a facilitator will contact them immediately, in person or via a phone, video call, or telephone call (their personal communication preference will have been ascertained and recorded during the consent process). Participants will be invited to talk with the facilitator and receive appropriate signposting for support.

Organisations to which participants can be signposted: will include

- Samaritans
- Shout
- Mind Info Line
- The Mix

The organisations are chosen to provide individuals with a choice of support, such as immediate crisis support, longer term mental health and distress support, as well as various ways to communicate, such as phone calls or text messaging services.

If at any point during the meetings or in conversations with people during the recruitment process the CHANGE facilitator or researcher has concerns about a safeguarding issue they will inform the CHANGE project lead immediately after the meeting/discussion. The CHANGE project lead will evaluate the level of concern and agree the action to be taken in accordance with CHANGE's safeguarding policy including whether escalation to the organisation's safeguarding lead is required. The CHANGE project lead will notify the CI and WMS project manager that a concern has been raised and any action taken. This will be recorded on the WMS study template for reporting concerns.

6.2.7 Data management

CHANGE will hold personal details for contacting participants and for workshop and reference group meeting organisation in a secure, password protected Excel spreadsheet. Contact details will not be transferred to the study team. Anonymised demographic information collected from participants will be held by CHANGE in a separate secure spreadsheet and transferred securely to the study team at Warwick for inclusion in the overall study. Any concerns participants have about their anonymised information being included in the study will be addressed by CHANGE when taking informed consent prior to data collection. Data from the reference group meetings and online workshops will be recorded by a University of Warwick researcher on an encrypted audio device for the purpose of supplementing anonymised fieldnotes made by the researcher. Recordings will be transferred securely to Warwick University on the same day where they will be stored as password protected files on the university server accessible only to the core study team. Fieldnotes will be uploaded to NVivo software for data management and analysis. Anonymised data will be shared with Leeds University via a data sharing agreement for the purpose of analysis. Anonymised summaries of workshops will be shared with CHANGE to inform and prepare subsequent workshops.

6.2.8 Analysis

Researchers will take notes at reference group meetings and workshops and audio record them for the purpose of supplementing fieldnotes. The supplemented fieldnotes will be analysed in NVivo using thematic analysis and memos will be used to record emerging themes and summaries of workshops. These outcomes/messages from each workshop will be discussed, reviewed and refined with the Reference Group and presented at the next workshop together with resources to inform the next workshop activities. The final reference group meeting will consider overall findings from the workshops and the recommendations/resources produced.

During their sessions the advisory group will collectively reflect on the process of co-production and the experience of working with the research team. We will use a method of collaborative autoethnography to explore and evaluate the advisory group's experiences of the workshop design process(99, 100).

6.3 Focus groups for carers of people with learning disability

6.3.1 Recruitment

We will work with CHANGE, other learning disability organisations and carers networks nationally to advertise the project to people caring for someone with a learning disability. We will provide a poster leaflet about the project and an invitation email describing the study for circulation through these groups. We will ask those interested in participating in a focus group or learning more about the study to contact the research team to express their interest. A researcher will contact anyone expressing an interest to explain more about the project and answer any questions. We will aim to conduct three focus groups (total approximately 20 participants).

6.3.2 Consent

The researcher will contact potential participants, answer any questions about the study and check that they are able to attend the focus group. We will send each participant a more detailed information sheet with a contact telephone number to use if they have any further questions. Two weeks prior to the focus group we will send participants a briefing pack about the ReSPECT programme and a summary of findings from initial analysis of WP1 data (patient and carer's experiences of ReSPECT). Remote verbal consent will be obtained by the researcher prior to the focus group as outlined above.

6.3.3 Data collection

Following the consent process the researcher will ask the participant to complete a brief demographic questionnaire with the person as outlined in WP2.

An experienced facilitator will conduct each focus group, with a researcher present to take notes. Prior to starting discussion, the facilitator will briefly revise the aims of the study and its context, present what was in the briefing pack as a reminder and to frame the discussion. Focus group members will be prompted to discuss the following questions:

- What are/might be the benefits for patients, carers, the health service, and wider society of the implementation of ReSPECT?
- What are/might be the benefits of ReSPECT for people with learning disabilities?
- What are/might be the dis-benefits of ReSPECT?
- Are there particular dis benefits/challenges for people with learning disabilities?
- What gets in the way/might get in the way of implementing ReSPECT in a way that optimises its use and value, including access to forms and transfer between health and social care organisations?
- How can the dis-benefits of ReSPECT, and challenges to its use be mitigated?

6.3.4 Data management

Focus group data will be managed in the same manner as described for interview data in WP1.

6.3.5 Analysis

We will adopt the same process for analysing focus groups with LD carers as for the focus groups in WP2. We will analyse these focus group data separately and in conjunction with the data from our other focus groups with the general public (WP2).

7. WP5 EVIDENCE SYNTHESIS AND STAKEHOLDER CONFERENCE (OBJECTIVES 3 AND 5)

Findings from our previous work packages will be synthesised in a process of triangulation to look for convergence and divergence within the overarching framework of NPT (how different stakeholders conceptualise, engage with and use the ReSPECT process). We will identify key findings and their associated implications for practice relevant to a) patients and families; b) health care professionals; and c) managers and policy makers. We will present our key findings at a stakeholder conference to be held at Warwick University. Participants invited will include members of patient and carer organisations, community and faith groups, relevant professional organisations, policy makers, and regulatory bodies, and members off the national ReSPECT working group. We will use the principles of experience-based co-design to inform the structure of the meeting (101). The meeting will commence with a formal presentation of the study findings, followed by an invited presentation from a senior member of the Resuscitation Council's ReSPECT sub committee which will outline the current ReSPECT implementation support strategy, including their suggested core audit criteria. Following the presentations, participants, working in facilitated mixed small groups, will listen to an film/audio recording created to illustrate touch points within the ReSPECT process. A touch point is talk that is emotionally significant. Touch points will be identified from across all our interview and focus group data. They will be identified during initial analysis in collaboration with our PPI panel. The audio clips of these touch points will be edited together for the stakeholder conference. At the conference, after listening to the audio the small groups will identify how ReSPECT implementation could be improved. After sharing these initial ideas in plenary, participants will work further in new facilitated mixed small groups to refine the key messages that have emerged from our findings to consider how identified

obstacles to implementation of ReSPECT in Primary Care can be overcome. We will specifically consider any identified challenges to involving minority or marginalised groups in the ReSPECT process and suggested mechanisms for successful embedding of ReSPECT in day-to-day primary care practice. Following the meeting the project team will draw on its conclusions to draft a suggested framework to support improved effective implementation of ReSPECT (and emergency care treatment plans more broadly). We will follow the process used successfully in a previous NIHR funded project on decision-making around admission to intensive care (102). Anticipated outputs will be:

- recommendations for training for primary care staff,
- a decision support framework for making emergency care and treatment decisions using ReSPECT, suggested audit criteria for quality assessment of the ReSPECT process,
- information/support materials for patients and families.

A draft report of the conference and suggested recommendations will be sent to all participants for further comment before finalising.

8. STUDY ORGANISATION AND OVERSIGHT

8.1 Sponsor and governance arrangements

The University of Warwick will act as the Sponsor for this study. Warwick standard operating procedures will be followed.

8.2 Ethical approval

All required ethical approval(s) for the trial will be sought using the Integrated Research Application System. The trial will be conducted in accordance with all relevant regulations.

Before enrolling patients into the study, the research team must ensure that the local conduct of the trial has the agreement of the relevant participating organisation as well as overarching HRA approval in place.

Substantial amendments to the protocol will be communicated to all relevant parties (i.e. investigators, sponsor, NIHR, REC, participating sites, local CRN).

Annual reports will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. The REC will be notified of the end of the trial (whether at planned time or prematurely).The CI will submit a final report to the required authorities with the results, including any publications within one year of the end of the study.

8.3 Trial Registration

The study will be eligible for inclusion on the CRN Portfolio.

8.4 Indemnity

NHS indemnity covers NHS staff for any actions performed as part of the study. The University of Warwick provides indemnity for any harm caused to participants by the design of the research protocol and conduct of the research by its staff

8.5 Project timetable and milestones

Tasks		**Set up**	**Year one**				**Year two**			
Liaison with HS&DR	**contracting**									
Management group meetings		**xxx**	**xxx**	**xxx**	**xxx**	**xxx**	**xxx**	**xxx**	**xxx**	**xxx**
Steering group meetings			**x**		**x**		**x**		**x**	
Lay advisory group meetings			**x**	**x**	**x**		**x**		**x**	
Ethics R&D and HRA approvals										
WP1&3 site recruitment										
WP1&3 site set up										
WP1	**Development of study manual & processes**									
Interviews	**Data collection**									
	Analysis									
WP2										
FGs/faith leader interviews	**Recruitment**									
	Data collection									
	Analysis									
Surveys	**Development of questions**									
	Data collection									
	Analysis									
WP3	**Development of study manual & processes**									
	Data collection									
	Analysis									
WP4	**Recruitment**									
	Data collection									
WP5	**Synthesis of findings from WPs1-3**									
	Stakeholder meeting									
	Development of suggestions for practice									
Report writing/dissemination										

Figure 2 Plan of investigation and timetable

Key milestones:

6 months: 4 sites open for data collection WPs1 & 3
12 months: 12 sites open for data collection;
18 months WP4 co production workshops in progress, surveys initiated
20 months: Analysis Wps1-3 complete, WPs 1&3 papers submitted
22 months WP 4 analysis complete, paper submitted
24 months Stakeholder conference held
26 months: Project report, survey paper and overall project paper submitted

8.6 Administration

The study co-ordination will be based at Warwick Medical School, University of Warwick.

8.7 Study Management Group (SMG)

The Study Management Group, consisting of the project staff and co-investigators involved in the day-to-day running of the trial, will meet regularly throughout the project. Significant issues arising from management meetings will be referred to the Study Steering Committee or Investigators, as appropriate.

8.8 Study Steering Committee (SSC)

The study will be guided by a group of respected and experienced personnel and researchers, as well as at least one 'lay' representative. The SSC will have an independent Chairperson. Meetings will be held at six monthly intervals throughout the project. Routine business is conducted by email, post or teleconferencing.

The Steering Committee, in the development of this protocol and throughout the study will take responsibility for:

- Major decisions such as a need to change the protocol for any reason
- Monitoring and supervising the progress of the study
- Reviewing relevant information from other sources
- Informing and advising on all aspects of the study

The full remit and responsibilities of the SSC will be documented in the Committee Charter which will be signed by all members.

8.9 Data Monitoring Committee (DMC)

Since there is no intervention delivered as part of the study, a DMC is not required.

8.10 Essential Documentation

A Study Master File will be set up according to WMS Standard Operating Procedures and held securely at the coordinating centre.

The coordinating centre will provide Investigator Site Files to all sites involved in the study.

8.11 Financial Support

The study has been funded by a grant from the National Institute for Health Research (NIHR) Health Services and Delivery Research programme.

9. MONITORING AND QA

All research staff involved in data collection for WP1, WP2 WP3 and WP4 will have had GCP training or University of Warwick research integrity training. Training will also be carried out for research staff who may answer phone calls from patients or legal representatives and need to deal sensitively with their questions.

All interviews will be conducted by the co-ordinating team Research Fellow(s). Consent procedures, interview schedules and a process for recording field notes will be developed and reviewed by researchers, PPI advisory group, and co-investigators responsible for each work package, ensuring a consistent, but flexible approach needed for this type of data collection.

Quality assurance during analysis of qualitative data: coding will be undertaken by independent researchers for 30% of transcripts and any inconsistency discussed to ensure consistency.

Data quality checks will have been done by the BSA and medeConnect GP Omnibus, according to their protocols, prior to transfer of the anonymised data set to University of Warwick for analysis.

Each site will receive an initiation visit where study training will be delivered by the co-ordinating centre researchers. Training will be recorded on a log and stored in the study master file.

After the initial site visits to each practice and care home, the study manager will have regular contact with the sites to identify any problems with compliance with the protocol, training, data collection, or other barriers to progress, and to support sites with the day-to-day management of the study. As well as regular telephone and email contact, and the co-ordinating centre researcher visiting for data collection, a site visit (conducted virtually be video conference) may be arranged if there are particular issues that are best resolved face to face. The study manager will check with each site that all Investigator Site File documents are up to date at least once during the study.

10. PPI INVOLVEMENT

The research was initially developed with the PPI group from our current ReSPECT evaluation study and this group have agreed to continue in this role for this study. Our PPI co-investigator will contribute to the day to day running and organisation of the study, in addition to reviewing patient information resources and contributing to final report writing and dissemination. He also has extensive experience of public engagement and advocacy in his role as Chief Executive of Health Watch Warwickshire. Further PPI input will be provided through two independent members of the Study Steering Committee. Our separate advisory group will be involved at all stages of the study, advising on patient and public facing documentation, contributing to analysis and interpretation of findings and active engagement in our stakeholder conference.

The co-production process in WP4 will be overseen by a reference group recruited by CHANGE from people with learning disability. The reference group will work with CHANGE and the wider study team to design the coproduction workshops. They will review/advise on findings from each workshop, integration of findings into overall study, and final outputs of the work package. They will meet eight times during the project and attend the stakeholder conference to present outputs

11. DISSEMINATION AND PUBLICATION

The results of the study will be reported first to study collaborators. The main report will be drafted by the study team, and the final version will be agreed by the Study Steering Committee before submission for publication, on behalf of the collaboration.

The success of the study depends on the collaboration of GPs, practice staff, and care home staff, from across the UK. Equal credit will be given to those who have wholeheartedly collaborated in the study.

The study will be reported in accordance with the relevant reporting guidelines (http://www.equator-network.org).

The output of this work will have maximal impact through the adoption of a dissemination strategy with three strands. The first will ensure that patients and public are informed of the study results; the second will engage practitioners and health care planners to implement the findings, and the third will involve consulting with policy makers for maximum impact.

Patients and the public: Patient and public understanding of the reasons for and process of emergency care treatment planning is an essential part of establishing the trust necessary to enable implementation of policy and practice. We will produce a plain English summary of the study findings that we will disseminate through patient and community organisations we have identified through the study in addition to national support groups such as Age-UK, Alzheimer's Society, and patient panels of professional organisations. We will work with our PPI group and also seek suggestions for contacts during our focus groups and interviews with faith leaders. We will seek the support of regional Health Watch organisations to disseminate in their areas. Our PPI Co-investigator, Bain, is chief executive of Warwickshire Health Watch and will provide links to other health watch organisations. We will work with actors to develop short videos of patient stories based on our data to be used as an educational and public information resource to be distributed through community groups and general practices. We will also post information about the study and its findings on NHS and University websites and social media. Specific resources developed as part of the co-production workshops will be disseminated through CHANGE and other learning disability organisations.

Practitioners: Through our contacts with the RCUK ReSPECT subcommittee we will disseminate our findings to local and regional ReSPECT implementation. We will work with the RCUK ReSPECT clinical lead and subcommittee to ensure emerging study findings are fed into training and support initiatives as early as possible. We will work with local and regional implementation teams in our study sites to develop brief information/training videos for practice staff and care home staff which can be disseminated through CCGs. We will disseminate our findings to primary care practitioners through presentations at regional and national meetings, web-based resources, and social media. We will submit our key findings to open access, high impact journals with a wide general readership (e.g. BMJ, BJGP, Health Service Journal).

Policy makers: We will continue engagement with key policy makers (NHS England, Department of Health, Clinical Commissioning Groups, Care Quality Commission) during this work with the aim of ensuring the project delivers information of value to any future changes to policy. The project will summarise the key successes and limitations of integrating ReSPECT in primary care. It will assist policy makers by providing an evidence base to inform the need for any changes or refinement to policy. Policy makers and managers will be invited to our stakeholder meeting.
The strategies for dissemination could have the following impacts.
For patients and the public, knowledge about the effects and impacts of emergency care and treatment plans could be used to enable them on a personal level to become more involved in decision-making about these aspects of their care. If emergency care and treatment plans do reduce inappropriate attempts at resuscitation and admission to hospital, it should increase the number of patients who

experience a peaceful death in the place of their preference. If patient and relative involvement in decision-making is improved. The knowledge about patient experience generated by the study could be used by individuals and patient and public organisations to inform to public discussion about anticipatory decision-making for emergency care and treatment.

For clinicians, we will specifically seek out exemplars as best practice to show case how emergency care treatment plans are best used to support ethical decision-making in partnership with patients and relatives. This will help to increase confidence in their use. Knowledge of enablers and potential obstacles to integration of emergency care treatment plans in primary care practice can prompt practitioners, managers and commissioners to consider structural and process changes that would enable them to be used more effectively. We anticipate our findings could be used to generate learning materials that can contribute to RCGP and Marie Curie training on the Daffodil standards for advanced serious illness and end of life care. We have experience of working with e Learning for Health and the Faculty of Intensive Care Medicine to develop e Learning modules based on previous research and will explore similar opportunities with the RCGP.
We anticipate that our findings will inform future development of support and educational resources developed by the RCUK ReSPECT team, and through their work with local and regional implementation leads will directly impact how ReSPECT is operationalised in primary care practice.

The project will contribute evidence to inform policy makers in considering whether and how to develop policy or recommendations on the use ECTPs at a national level.

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